

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 335 357 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
08.05.1996 Bulletin 1996/19

(51) Int. Cl.⁶: **A61B 5/00**

(21) Application number: 89105502.2

(22) Date of filing: 29.03.1989

(54) Improved method and apparatus for detecting optical pulses

Verbessertes Verfahren und Gerät zur Messung optischer Impulse

Méthode améliorée et appareil pour détecter des impulsions optiques

(84) Designated Contracting States:
AT BE CH DE FR GB LI LU NL

(30) Priority: 30.03.1988 US 175152

(43) Date of publication of application:
04.10.1989 Bulletin 1989/40

(73) Proprietor: **NELLCOR INCORPORATED**
Hayward California 94545 (US)

(72) Inventors:
• Goodman, David E.
San Francisco California 94117 (US)
• Briggs, Deborah A.
San Ramon California 94583 (US)

• Boross, Andras
Fremont California 94583 (US)
• Corenman, James E.
Oakland California 94611 (US)
• Stone, Robert T.
Sunnyvale California 94087 (US)

(74) Representative: **VOSSIUS & PARTNER**
Postfach 86 07 67
81634 München (DE)

(56) References cited:
WO-A-86/05674 WO-A-88/01148
US-A- 4 167 331

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 335 357 B1

Description

This invention relates to non-invasive pulse oximetry and specifically to an improvement on the method and apparatus for photoelectric determination of blood constituents disclosed in WO 86/05674.

Non-invasive photoelectric pulse oximetry has been previously disclosed in US-A-4,407,290, US-A-4,266,554, US-A-4,086,915, US-A-3,998,550, US-A-3,704,706, EP-A-102,816 EP-A-104,772 and EP-A-104,771. Pulse oximeters are commercially available from Nellcor Incorporated, Hayward, California, U.S.A., and are known as, for example, Pulse Oximeter Model N-100 (herein "N-100 oximeter").

Pulse oximeters typically measure and display various blood flow characteristics including but not limited to blood oxygen saturation of hemoglobin in arterial blood, volume of individual blood pulsations supplying the flesh, and the rate of blood pulsations corresponding to each heartbeat of the patient. The oximeters pass light through human or animal body tissue where blood perfuses the tissue such as a finger, an ear, the nasal septum or the scalp, and photoelectrically sense the absorption of light in the tissue. The amount of light absorbed is then used to calculate the amount of blood constituent being measured.

The light passed through the tissue is selected to be of one or more wavelengths that is absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of transmitted light passed through the tissue will vary in accordance with the changing amount of blood constituent in the tissue and the related light absorption.

For example, the N-100 oximeter is a microprocessor controlled device that measures oxygen saturation of hemoglobin using light from two light emitting diodes ("LED'S"), one having a discrete frequency of about 660 nanometers in the red light range and the other having a discrete frequency of about 925 nanometers in the infrared range. The N-100 oximeter microprocessor uses a four-state clock to provide a bipolar drive current for the two LED'S so that a positive current pulse drives the infrared LED and a negative current pulse drives the red LED to illuminate alternately the two LED'S so that the incident light will pass through, e.g., a fingertip, and the detected or transmitted light will be detected by a single photodetector. The clock uses a high strobing rate, e.g., one thousand five hundred cycles per second, to be easily distinguished from other light sources. The photodetector current changes in response to the red and infrared light transmitted in sequence and is converted to a voltage signal, amplified, and separated by a two-channel synchronous detector -- one channel for processing the red light waveform and the other channel for processing the infrared light waveform. The separated signals are filtered to remove the strobing frequency, electrical noise, and ambient noise and then digitized by an analog to digital converter ("ADC"). As used herein, incident light and transmitted light refers to light generated by the LED or other light source, as distinguished from ambient or environmental light.

The light source intensity may be adjusted to accommodate variations among patients' skin color, flesh thickness, hair, blood, and other variants. The light transmitted is thus modulated by the absorption of light in the variants, particularly the arterial blood pulse or pulsatile component, and is referred to as the plethysmograph waveform, or the optical signal. The digital representation of the optical signal is referred to as the digital optical signal. The portion of the digital optical signal that refers to the pulsatile component is labeled the optical pulse.

The detected digital optical signal is processed by the microprocessor of the N-100 oximeter to analyze and identify arterial pulses and to develop a history as to pulse periodicity, pulse shape, and determined oxygen saturation. The N-100 oximeter microprocessor decides whether or not to accept a detected pulse as corresponding to an arterial pulse by comparing the detected pulse against the pulse history. To be accepted, a detected pulse must meet certain predetermined criteria, for example, the expected size of the pulse, when the pulse is expected to occur, and the expected ratio of the red light to infrared light of the detected optical pulse in accordance with a desired degree of confidence. Identified individual optical pulses accepted for processing are used to compute the oxygen saturation from the ratio of maximum and minimum pulse levels as seen by the red wavelength compared to the maximum and minimum pulse levels as seen by the infrared wavelength.

Several alternate methods of processing and interpreting optical signal data have been disclosed in the patents and references cited above.

A problem with non-invasive pulse oximeters is that the plethysmograph signal and the optically derived pulse rate may be subject to irregular variants in the blood flow, including but not limited to motion artifact, that interfere with the detection of the blood flow characteristics. Motion artifact is caused by the patient's muscle movement proximate to the oximeter sensor, for example, the patient's finger, ear or other body part to which the oximeter sensor is attached, and may cause spurious pulses that are similar to pulses caused by arterial blood flow. These spurious pulses, in turn, may cause the oximeter to process the artifact waveform and provide erroneous data. This problem is particularly significant with infants, fetuses, or patients that do not remain still during monitoring.

A second problem exists in circumstances where the patient is in poor condition and the pulse strength is very weak. In continuously processing the optical data, it can be difficult to separate the true pulsatile component from artifact pulses and noise because of a low signal to noise ratio. Inability to reliably detect the pulsatile component in the optical signal may result in a lack of the information needed to calculate blood constituents.

It is well known that electrical heart activity occurs simultaneously with the heartbeat and can be monitored externally and characterized by the electrocardiogram ("ECG") waveform. The ECG waveform, as is known to one skilled in the art, comprises a complex waveform having several components that correspond to electrical heart activity. The QRS component relates to ventricular heart contraction. The R wave portion of the QRS component is typically the steepest wave therein, having the largest amplitude and slope, and may be used for indicating the onset of cardiovascular activity. The arterial blood pulse flows mechanically and its appearance in any part of the body typically follows the R wave of the electrical heart activity by a determinable period of time that remains essentially constant for a given patient. See, e.g., Goodlin et al., "Systolic Time Intervals in the Fetus and Neonate", *Obstetrics and Gynecology*, Vol. 39, No. 2, February 1972, where it is shown that the scalp pulse of fetuses lag behind the ECG "R" wave by 0.03-0.04 second, and U.S. Patent 3,734,086.

In WO 86/05674, there is disclosed an invention for measuring the patient's heart activity and correlating it with the patient's detected blood flow signals to calculate more accurately the patient's oxygen saturation and pulse rate. The correlation includes auto- and cross correlation techniques to enhance the periodic information contained in each individual waveform as well as determine the time relationship of one waveform to another.

Correlating the occurrence of cardiovascular activity with the detection of arterial pulses occurs by measuring an ECG signal, detecting the occurrence of the R-wave portion of the ECG signal, determining the time delay by which an optical pulse in the detected optical signal follows the R-wave, and using the determined time delay between an R-wave and the following optical pulse so as to evaluate arterial blood flow only when it is likely to present a true blood pulse for waveform analysis. The measured time delay is used to determine a time window when, following the occurrence of an R-wave, the probability of finding an optical pulse corresponding to a true arterial pulse is high. The time window provides an additional criterion to be used in accepting or rejecting a detected pulse as an optical pulse. Any spurious pulses caused by motion artifact or noise occurring outside of that time window are typically rejected and are not used to calculate the amount of blood constituent. Correlating the ECG with the detected optical pulses thereby provides for more reliable measurement of oxygen saturation.

That publication refers to a modified N-100 oximeter (the "enhanced N-100 oximeter") whereby the device is provided with an additional heart activity parameter in the form of a detected R-wave from the patient's ECG waveform, in addition to the N-100 pulse oximeter functions, and the microprocessor is modified to include software and memory for controlling and processing the optical signal and heart activity information.

The additional heart activity parameter is independent of the detection of peripheral arterial pulses, e.g., ECG signals, ultrasound, ballistocardiogram, and maybe, accelerometers, nuclear magnetic resonators, electrical impedance techniques, and the like, and provides an identifiable and detectable signal in response to each heartbeat for use by the signal processing of the oximeter.

It is an object of this invention to provide for improved processing of the detected optical signal containing periodic information corresponding to arterial pulsatile blood flow and aperiodic information corresponding to noise, spurious signals, and motion artifact unrelated to the beating heart and arterial pulsatile blood flow, to improve further the reliability and accuracy of the determination of blood constituent, particularly oxygen saturation of hemoglobin by a non-invasive oximeter device.

It is another object of this invention to provide an improved method and apparatus for collecting successive portions of detected optical signals encompassing periodic information for more than one heartbeat and processing the collected portions to attenuate and filter therefrom aperiodic signal waveforms to provide enhanced periodic information from which the patient's blood constituent can be accurately determined.

It is another object to maintain the enhanced periodic information updated by continuing to add new portions of detected optical signals as they are obtained.

It is another object of this invention to evaluate the collected periodic information for a predetermined number of successive portions of the detected optical signal corresponding to a predetermined number of heartbeats in the frequency domain to obtain enhanced periodic information.

It is another object of this invention to Fourier transform a time-measure of detected optical signals including periodic information for N heartbeats to determine the relative maxima at the fundamental frequency N and the minima at the zero frequency for use in determining the light modulation ratio for the amount of blood constituents.

It is another object of this invention to correlate the Fourier Transform of the time-measure of detected optical signals with the Fourier Transform of a time-measure of the ECG signal, and more particularly the R-wave events of the ECG signal, to determine the maxima at the fundamental heart frequency.

It is another object of this invention to correlate the periodic information in a time-measure of the detected optical signal with a time-measure of the detected heart activity, preferably in the form of the ECG signal and more preferably in the form of the R-wave of the ECG signal, to define a predetermined number of samples in a data set and use frequency domain analysis techniques to evaluate the collected predetermined number of sample data sets to determine the relative maxima at the fundamental frequency.

This invention provides enhanced periodic information with improved rejection of noise, spurious pulses, motion artifact, and other undesired aperiodic waveforms and thereby improves the ability of oximeters to accurately determine amounts of blood constituents.

The present invention provides methods and apparatus for collecting a time-measure of the detected optical signal waveform containing a plurality of periodic information corresponding to arterial pulses caused by the patient's heartbeat and aperiodic information unrelated to pulsatile flow, and processing the collected time-measure of information to obtain enhanced periodic information that is closely related to the most recent arterial pulsatile blood flow. The time-measure may comprise a continuous portion of detected optical signals including a plurality of periodic information from successive heartbeats, or a plurality of discrete portions of detected optical signals including a corresponding plurality of periodic information.

By updating the time-measure of information to include the most recently detected periodic information, and processing the updated measure collectively, an updated enhanced periodic information is obtained (including the new and historical data) from which aperiodic information (including any new aperiodic information) is attenuated. Applicants have discovered that by collectively processing a time-measure including successive periodic information to obtain the enhanced periodic information, and using the enhanced periodic information as the basis for making oxygen saturation calculations, the accuracy and reliability of oxygen-saturation determinations can be significantly increased.

Applicants also have discovered that a time-measure of detected optical signals containing a plurality of periodic information corresponding to successive heartbeats can be collectively processed and analyzed using frequency domain techniques. These frequency domain techniques utilize the synchronous nature of the heartbeat and the asynchronous characteristics of noise, spurious signals, and motion artifacts.

The amount of a blood constituent, for example, oxygen saturation, can be then determined from this enhanced periodic information (also referred to as composite signal information) by determining the relative maxima and minima in the enhanced periodic information for the respective wavelengths for use in determining the modulation ratios of the known Lambert-Beers equations.

In the preferred embodiment, the detected optical signals are conventionally obtained by passing red (660 nanometers) and infrared (910 nanometers) light through a patient's blood perfused tissue, detecting the transmitted light which is modulated by the blood flow, and providing red and infrared detected optical signals that are preferably separately processed and optionally converted from analog to digital signals, for example, as described above for the Nellcor N-100 oximeter. Portions of the corresponding red and infrared digital signals are then collectively processed in accordance with the present invention and the light modulation ratios are determined based on the resulting enhanced periodic information and used to calculate oxygen saturation.

In the frequency domain, the optical signals for a given wavelength corresponding to the pulsatile arterial blood flow have spectral components including a zero frequency at the background intensity level, a fundamental frequency at the frequency of the beating heart, and additional harmonic frequencies at multiples of the fundamental frequency. Noise, spurious signals, and motion artifact that appear in the detected optical signal have frequencies that spread across the spectrum. Transient changes in the average background intensity level have frequencies that appear spread out between the zero frequency and the fundamental frequency.

The present invention provides a method and apparatus for collecting a time-measure of detected optical signals including a predetermined number of optical pulses, converting the collected detected optical signals into the frequency domain, and analyzing the spectral components of the frequency spectrum thereby to determine the red and infrared relative maxima intensity at the fundamental frequency, and relative minima at the background intensity zero frequency, for use as maxima and minima in the percentage modulation ratio for calculating oxygen saturation.

Applicants have discovered that if the digitized values of the time domain detected optical signals are stored in memory for a period of N heartbeats, and the stored data set is transformed into the frequency domain using Fourier Transforms, the amplitude of the fundamental heart rate is summed for the N heartbeats and appears in the frequency spectrum at a location of N cycles. In contrast, the amplitude of asynchronous signals is $1/m$, where m is the number of data points in the digitized stored data set, and appear spread across the frequency domain spectrum. The average intensity of the detected optical signal background intensity appears at the spectral line corresponding to zero cycles and corresponds to the average background intensity for that wavelength.

If the detected optical signal for the red and infrared signals is considered as a single complex data set, i.e., having real and imaginary components, only a single Fourier transform is required to analyze the spectral contents of the collective time-measure of the two signals. If $F(s)$ represents the Fourier Transform of the complex data set $f(t) = \text{Red}(t) + j\text{IR}(t)$ (for $\text{Red}(t)$ being the red detected optical signal and $\text{IR}(t)$ being the infrared detected optical signal), the Fourier Transform of the real component of $f(t)$ is found by

$$F[\text{Re}\{f(t)\}] = 1/2[F(s) + F^*(-s)].$$

Similarly, the Fourier transform of the imaginary component of $f(t)$ is found by

$$F\{\text{Im}[f(t)]\} = 1/2\{F(s) - F^*(-s)\}.$$

$F^*(-s)$ is the complex conjugate of $F(s)$ with the index s reversed.

The relative amplitudes of the red and infrared fundamentals at the heartrate may be found by searching the frequency spectrum in the region of expected heart rates for a relative maximum and insuring that this is the fundamental by determining the existence of another relative maximum at twice this rate. This provides a technique for obtaining relative modulation data to calculate arterial oxygen saturation without the need to identify the heart rate independently, e.g., by detecting the ECG. Alternately, the amplitude data at the fundamental may be found by the use of independent heart rate determining mechanism such as ECG or phonoplethysmography or the like to determine a heart rate. However, unlike the time domain techniques, the precise time of occurrence of each heartbeat need not be determined and the optical signal and a heart rate parameter need not be correlated to obtain accurate saturation values. Rather, it is sufficient to obtain an approximate indicator of heart rate, which will facilitate identification of the fundamental frequency and improve saturation reliability.

The number of spectral lines computed is preferably optimized to include the expected range of clinically applicable heartbeats (from 20-250 beats per minute), while the length of the data set is selected by the allowable equivalent delay in displaying measured arterial oxygen saturation. A time-measure of data of, for example, 9-10 seconds represent delays of only 4-5 seconds in the display of computed saturations, and, depending upon the computational speed of the oximeter microprocessor, the time-measure can be updated in timely fashion every 1 to 2 seconds.

In the preferred embodiment, the optical signal is digitized at 57 samples per second for each red and infrared signal. When 512 data points are accumulated, the data is Fourier transformed, and the red and infrared fundamental maxima are located. The percentage modulation ratio (red/infrared) is computed by dividing the energy at each maxima by the zero cycle background intensity for that wavelength, then dividing the red modulation by the infrared modulation. The resultant ratio, R , is then used in the manner set forth in the Lambert-Beers equations for calculating arterial saturation of hemoglobin. The collective data can be updated so that new data points replace the oldest data points by using a push down stack memory or equivalent so that the transform, evaluation and saturation calculation could be made after each new data set was obtained.

An alternative embodiment of the frequency domain analysis technique includes sampling the real time ECG waveform and the real time detected optical signal at high rates, e.g. 1000 samples per second. By examining the ECG wave, the time of occurrence for each heartbeat and the appropriate sample rate to obtain m samples during that heartbeat could be determined. Thus, the data set for each heartbeat can be selected to contain the same number of m samples, where each sample is a fraction of the heartbeat period, and N heartbeats contains mxN samples. Taking the Fourier transform of this mxN data set and processing the spectral components of the transform in the same manner as described previously, results in a spectral analysis having several additional advantages. First, the fundamental maximum would always occur at the spectral line for N cycles in "heartbeat" space. Second, any signal present in the data set which did not remain synchronous with the heart, including noise, artifact and transient background intensity changes, would be spread over the heartbeat spectrum. Third, the enhancement in signal-to-noise would be the same for all heart rates. Fourth, because only two spectral lines are of interest, the zero spectral line corresponding to the zero frequency background intensity and the N spectral line corresponding to the number of heartbeats for the data set, the Fourier Transform need only be made at the two frequency components and not of the entire spectrum, and the computation efforts required by the microprocessor are significantly diminished.

The apparatus of the present invention includes inputs for the plethysmographic detected optical signals and, optionally, ECG signals of a patient, an analog to digital converter for converting the analog plethysmographic signal to the digital optical signals and for converting the analog ECG signals into digital ECG signals (unless the plethysmographic or ECG signals are provided in digital form), and a digital signal processing section for receiving the digital signals and processing the digital detected optical signal in accordance with one of the foregoing analysis techniques of the present invention, including a microprocessor, memory devices, buffers, software for controlling the microprocessor, and display devices.

In its context, the apparatus of the present invention is a part of an oximeter device which has the capability to detect the red and infrared light absorption, and receive an ECG signal from the patient. In the preferred embodiment, the apparatus of this invention is a part of the Nellcor N-200 Pulse Oximeter (herein the "N-200 oximeter"), a commercially available noninvasive pulse oximeter device manufactured and sold by Nellcor, Incorporated, Hayward, California U.S.A.

The N-200 oximeter is an improved version of the enhanced N-100 oximeter described above and in International Publication No. WO86/05674. The N-200 includes circuits that perform many of the same functions as in the N-100 device, but includes some changes, for example, to expand the dynamic range of the device over the N-100 device and to include a 16 bit microprocessor manufactured by Intel Corporation, Model No. 8088. The N-100 oximeter uses an 8 bit microprocessor manufactured by Intel Corporation, Model 8085. The N-200 oximeter includes software for controlling the microprocessor to perform the operations of the conventional oximeter functions, and has some structure and processing methods that are unrelated to the present invention, and therefore are not discussed herein. The software could be modified to perform the frequency domain analysis techniques of the present invention.

The invention is described in detail in connection with the drawings in which

Figs. 1A and 1B are a block diagram of the apparatus of this invention and the apparatus associated with the present invention.

Fig. 2A is a detailed circuit schematic of the saturation preamplifier in the patient module of Fig. 1.

Fig. 2B is a detailed circuit schematic of the ECG preamplifier and input protection circuit in the patient module of Fig. 1.

Figs. 3A and 3B are a detailed circuit schematic of the saturation analog front end circuit of Fig. 1.

Fig. 4 is a detailed circuit schematic of the LED drive circuit of Fig. 1.

Fig. 5 is a detailed circuit schematic of the ECG analog front end circuit of Fig. 1.

Figs. 6A and 6B are a detailed circuit schematic of the analog to digital converter section of Fig. 1.

Figs. 7A, 7B and 7C are a detailed circuit schematic of the digital signal processing section of Fig. 1.

Fig. 8 is a detailed circuit schematic of the external ECG circuitry of Fig. 1.

Fig. 9 is a flow chart for the frequency domain optical pulse processing of this invention.

Figs. 10A, 10B, 10C, 10D and 10E are a series of waveforms corresponding to the flow chart of Fig. 10.

Referring to Figs. 1A and 1B, the preferred embodiment of the present invention relates to the apparatus for processing the detected analog optical signal and the analog ECG signal and comprises portions of analog to digital conversion section ("ADC converter") 1000 and digital signal processing section ("DSP") 2000, including the software for driving microprocessor 2040, which processes the digitized optical signals and ECG signals to determine the oxygen saturation of hemoglobin in arterial blood. Associated with the invention, but not forming a part of the invention, is the apparatus for obtaining the detected analog optical signals and the analog ECG signals from the patient that is part of or is associated with the commercially available Nellcor N-200 Pulse Oximeter. Such apparatus include plethysmograph sensor 100 for detecting optical signals including periodic optical pulses, patient module 200 for interfacing plethysmograph sensor 100 and the conventional ECG electrodes with saturation analog front end circuit 300 and ECG analog front end circuit 400 respectively, saturation analog circuit 300 for processing the detected optical signals into separate red and infrared channels that can be digitized, and ECG analog front end circuit 400 for processing the ECG signal so that it can be digitized. The N-200 oximeter also includes external ECG input circuit 500 for receiving an external ECG signal and processing the signal so that it is compatible with the N-200 processing techniques (as explained below), LED drive circuit 600 for strobing the red and infrared LEDs in plethysmograph sensor 100 at the proper intensity to obtain a detected optical signal that is acceptable for processing, and various regulated power supplies (not shown) for driving or biasing the associated circuits, as well as ADC 1000 and DSP 2000, from line current or storage batteries.

The associated elements are straightforward circuits providing specified functions which are within the skill of the ordinary engineer to design and build. The associated elements are briefly described here, and reference is made to the corresponding detailed schematics in the Figures and circuit element tables set forth below, to place the apparatus for using the present invention in its operating context in the preferred embodiment.

In the preferred embodiment, the invention requires two input signals, the two plethysmograph or detected optical signals (e.g., red and infrared) and, optionally, a third signal, the ECG signal of the patient. If analog signals are provided, they must be within or be adjusted by, for example, offset amplifiers, to be within the voltage input range for the ADC. In circumstances where the signals have been digitized already, they must be bit compatible with the digital signal processing devices, DSP.

The plethysmograph signal is obtained in a conventional manner for a non-invasive oximeter, typically by illuminating the patient's tissue with red and infrared light in an alternating fashion, in the manner described above for the N-100 oximeter. Referring to Figs. 1A and 1B, sensor circuit 100 has red LED 110 and infrared LED 120 connected in parallel, anode to cathode, so that the LED drive current alternately illuminates one LED and then the other LED. Circuit 100 also includes photodetector 130, preferably a photodiode, which detects the level of light transmitted through the patient's tissue, e.g., finger 140, as a single, analog optical signal containing both the red and infrared light plethysmographic, detected optical signal waveforms.

Referring to Figs. 1A, 1B, 2A, and 2B, patient module 200 includes preamplifier 210 for preamplifying the analog detected optical signal of photodetector 130, ECG preamplifier 220 for preamplifying the analog ECG signal detected from the ECG electrodes that would be attached to the patient in a conventional manner, and protection circuitry 250 interposed between instrumentation amplifier 220 and inverter 230 and the three ECG signal leads, to prevent high voltage transients from damaging the ECG preamplifier electronics.

Preamplifier 210 may be an operational amplifier configured as a current to voltage converter, biased by a positive voltage to extend the dynamic range of the system, thereby converting the photocurrent of photodiode 130 into a usable voltage signal. ECG preamplifier 220 is preferably a high quality instrumentation amplifier which amplifies the differential signal present on the two ECG signal electrodes. The common-mode signal present on the two signal electrodes is inverted by inverter 230 and returned to the patient by the third ECG lead, effectively nulling the common-mode signals. A biasing network on the two ECG signal leads is provided to aid in the detection of when an ECG electrode lead

becomes disconnected from patient module 200 or the patient. Patient module 200 also includes leads for passing the LED drive voltages to LEDs 110 and 120.

Referring to Figs. 1A, 1B, 3A and 3B, saturation analog front end circuit 300 receives the analog optical signal from patient module 200 and filters and processes the detected signal to provide separate red and infrared analog voltage signals corresponding to the detected red and infrared optical pulses. The voltage signal is passed through low pass filter 310 to remove unwanted high frequency components above, for example, 100 khz, AC coupled through capacitor 325 to remove the DC component, passed through high pass filter 320 to remove any unwanted low frequencies below, for example, 20 hertz, and passed through programmable gain stage 330 to amplify and optimize the signal level presented to synchronous detector 340.

Synchronous detector 340 removes any common mode signals present and splits the time multiplexed optical signal into two channels, one representing the red voltage signals and the other representing the infrared voltage signals. Each signal is then passed through respective filter chains having two 2-pole 20 hertz low pass filters 350 and 360, and offset amplifier 370 and 380. The filtered voltage signals now contain the signal information corresponding to the red and infrared detected optical signals. Additionally, circuits for use in preventing overdriving the amplifiers in saturation circuit 300 may be applied, for example, level-sensing circuits 312 and 314 (located after low pass filter 310) for indicating unacceptable LED drive current, and level sensing circuit 315 (located after programmable gain amplifier 330) for indicating unacceptable input amplifier gain setting.

Referring to Figs. 1A, 1B, and 5, ECG analog front end circuit 400 receives the preamplified ECG signal from patient module 200 and processes it for use with the present invention. The analog ECG signal is passed through 2-pole 40 hertz low pass filter 410 for removing unwanted frequencies above 40 hertz, and programmable notch filter 420 for removing unwanted line frequency components. Optionally, circuitry may be provided to measure the line frequency and to select an appropriate clock frequency for the notch filter. The ECG signal is then passed through low pass filter 430, preferably configured to remove further unwanted components above about 40 hertz, and in particular any frequency components that may have been generated by notch filter 420. Thereafter, the ECG signal is passed through 2-pole 0.5 hertz high pass filter 440 to remove any low-frequency baseline shifts present in the original ECG signal, and then passed through offset amplifier 450 to add an offset voltage so that the voltage is within the input signal specifications of the analog to digital converter device and the complete waveform will be properly digitized.

It also is desirable to pass the signal output from low pass filter 410 into a circuit that detects whether or not the ECG signal is being detected to identify a "leads-off" condition. The signal voltage is passed through absolute value circuit 480 to take the absolute value of the low pass filter output voltage and sends the value to comparator 490. Comparator 490 compares the absolute value voltage to a reference threshold or range and, when the absolute value voltage is not within the acceptable range, comparator 490 changes state which change is input to latch 495, to indicate this condition to, for example, the microprocessor.

Referring to Figs. 1A, 1B, and 8, the Nellcor N-200 device also is equipped with external ECG circuit 500 for receiving the ECG signal of a stand alone ECG detector device and processing the ECG signal so that it can be used with the N-200 oximeter and the present invention. Circuit 500 receives the external analog ECG signal, passes it across capacitor 510 to remove any DC offset voltage and then passes the signal through peak detection circuit 530. A portion of the AC coupled signal also is passed through buffer amplifier 520 and input to comparator 570. The held peak voltage is used as the reference threshold voltage that is fed to the other input of comparator 570 so that subsequent QRS complexes in the ECG signal that rise above the threshold generate a trigger signal that is transferred to DSP 2000 by an electrically isolated optical serial communication link comprising serial driving opto-isolator 580, electrically isolated optical link 590, and corresponding serial driving opto-isolator 2590 in DSP 2000.

Referring to Figs. 1A, 1B, 6A, and 6B, ADC 1000 provides the analog to digital conversions required by the N-200 oximeter. The aforementioned three voltage signals, the red detected optical signal, the infrared detected optical signal, and the ECG signal (preferably the ECG signal from patient module 200), are input to ADC 1000. These three signals are conventionally multiplexed and digitized by an expanded range 12-bit analog to digital conversion technique, yielding 16-bit resolution. The input signals are passed through multiplexor 1010 and buffer amplifier 1020. The converter stage includes offset amplifier 1030, programmable gain circuitry 1040 which allows a portion of the signal to be removed and the remainder to be further amplified for greater resolution, sample and hold circuit 1050, comparator 1060, and 12-bit digital to analog converter 1080. The buffered signal is passed through offset amplifier 1030 to add a DC bias to the signal wherein a portion of the signal is removed and the balance is amplified by being passed through programmable gain circuitry 1040 to improve the resolution. The amplified signal is then passed through sample and hold circuit 1050, the output of which is fed to one input of comparator 1060. The other input of comparator 1060 is the output of digital to analog ("DAC") converter 1080 so that when the inputs to comparator 1060 are the same, the analog voltage at the sample and hold circuit is given the corresponding digital word in DAC converter 1080 which is then stored in an appropriate memory device as the digitized data for the sample, and the next sample is sent to sample and hold circuit 105 to be digitized.

Referring to Figs. 1A, 1B, 4, 6A, 6B, 7A, 7B, and 7C, DAC 1080 also generates the sensor LED drive voltages, under the control of microprocessor 2040, using analog multiplexor 610, which separates the incoming analog signal into one

of two channels for respectively driving the red and infrared LEDs, having respective sample and hold circuits 620 and 630, and LED driver circuit 640 for converting the respective analog voltage signals into the respective positive and negative bipolar current signals for driving LEDs 110 and 120.

Alternate techniques of converting the analog signals to digital signals could be used, for example, a 16-bit analog to digital converter.

Referring to Figs. 1A, 1B, 7A, 7B, and 7C, DSP 2000 controls all aspects of the signal processing operation including the signal input and output and intermediate processing. The apparatus includes 16-bit microprocessor 2040 and its associated support circuitry including data bus 10, random access memory (RAM) 2020, read only memory (ROM) 2030, a conventional LED display device 2010 (not shown in detail), system timing circuit 2050 for providing the necessary clock synchronizing and notch filter frequency signals. In the preferred embodiment, microprocessor 2040 is a model 8088 microprocessor manufactured by Intel Corporation, Santa Clara, California. Alternate microprocessors may be used, such as any of model nos. 8086, 80186, and 80286, also made by Intel Corporation.

Referring to Figs. 9, 10A, 10B, 10C, 10D, 10E, the flow chart for the software operation of the preferred embodiment of the present invention are shown. A corresponding software written in the Asyst computer language, which is a commercially available language, is published in EP-A-335 357.

The routine begins at 4000 with the acquisition of 512 data points for each of the digitized red and infrared optical signals, which are shown graphically at Fig. 10A. At 4010, the complex data set, $f(t) = \text{Red}(t) + j\text{IR}(t)$, is formed. At 4020, the "D.C." component is formed by summing all of the data points, and the "D.C." component is then removed from the complex data set by subtraction at 4030, which is graphically shown at Fig. 10B. The resulting data is then decimated in time to 64 samples at 4040, which is illustrated in Fig. 10C, and the time decimated data is then processed by the Hamming Window function at 4050, which result is illustrated in Fig. 10D. Thereafter, the Fourier Transform is taken at 4060. The spectral components of the transform are shown in Fig. 10E. The Fourier Transforms of the red and infrared components are then calculated at 4070 in accordance with the aforementioned equations, and at 4080 the maximum value at the fundamental heart rate and the minimum value at the zero frequency are determined for each of the red and infrared transforms. The saturation ratio R is calculated as:

$$R = \frac{\text{peak at heartrate for red}}{\text{peak at heartrate for infrared}} = \frac{\text{Re("D.C.")}}{\text{Im("D.C.")}}$$

The minimum values for the red and infrared waveforms are taken from the respective real and imaginary components of the "D.C." component. Thereafter, the pulse data is declared ready and saturation is calculated in accordance with the known saturation formula. With each occurrence of the heartbeat, new data is acquired, the 512 data point set is updated and the routine operates to determine the saturation ratio R.

In the preferred embodiment, the blood constituent measured is the oxygen saturation of the blood of a patient. The calculation of the oxygen saturation is made based on the ratio of the pulse seen by the red light compared to the pulse seen by the infrared light in accordance with the following equation:

$$\text{Saturation} = 100\% \times \frac{BR2 - R(BR1)}{R(BO1 - BR1) + BR2 - BO2}$$

wherein

BO1 is the extinction coefficient for oxygenated hemoglobin at light wavelength 1 (Infrared)

BO2 is the extinction coefficient for oxygenated hemoglobin at light wavelength 2 (red)

BR1 is the extinction coefficient for reduced hemoglobin at light wavelength 1

BR2 is the extinction coefficient for reduced hemoglobin at light wavelength 2

light wavelength 1 is infrared light

light wavelength 2 is red light

and R is the saturation ratio as defined above.

The various extinction coefficients are determinable by empirical study as is well known to those of skill in the art. For convenience of calculation, the natural log of the ratios may be calculated by use of the Taylor expansion series for the natural log.

Circuit Tables

| | <u>REF #</u> | <u>CHIP</u> | <u>MFR PART #</u> | <u>Manufacturer</u> | <u>DESCRIPTION OF CHIP</u> |
|----|--------------|-------------|-------------------|------------------------|----------------------------|
| 5 | FIG. 2 | | | | |
| | 210 | U2 | LF442 | NATIONAL SEMICONDUCTOR | DUAL LOW POWER OP AMP |
| | 220 | U1 | INA101HP | BURR BROWN | INSTRUMENTATION AMP |
| 10 | 230 | U2 | LF442 | NATIONAL SEMICONDUCTOR | DUAL LOW POWER OP AMP |
| | FIG. 3. | | | | |
| | 312 | U27 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 15 | 312 | U28 | LP365N | NATIONAL SEMICONDUCTOR | QUAD VOLTAGE COMPARATOR |
| | 310 | U27 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| | 320 | U27 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 20 | 330 | U44 | MP7524LN | MICROPOWER | 8-BIT DAC |
| | 330 | U32 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| | 330 | U32 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 25 | 315 | U20 | LP365N | NATIONAL SEMICONDUCTOR | QUAD VOLTAGE COMPARATOR |
| | 340 | U32 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 30 | 340 | U14 | DG243CJ | SILICONIX INCORPORATED | ANALOG SWITCH |
| | 340 | U7 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| | 340 | U13 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 35 | 350 | U7 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| | 360 | U13 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 40 | | | | | |
| 45 | | | | | |
| 50 | | | | | |
| 55 | | | | | |

| | | | | |
|--------|-----|-----------|----------------|-------------------------------|
| 370 | U7 | LF444 | NATIONAL | QUAD JFET OP AMP |
| 380 | U13 | LF444 | SEMICONDUCTOR | |
| 340 | U19 | DG211CJ | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| | | | SILICONIX | CMOS ANALOG SWITCH |
| | | | INCORPORATED | |
| FIG. 4 | | | | |
| 640 | U19 | DG211CJ | SILICONIX | CMOS ANALOG SWITCH |
| | | | INCORPORATED | |
| 640 | U32 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| FIG. 5 | | | | |
| 410 | U12 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 420 | U6 | LTC1059CN | LINEAR | SWITCHED CAPACITOR FILTER |
| | | | TECHNOLOGY | |
| 430 | U12 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 440 | U12 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 440 | U19 | DG211CJ | SILICONIX | CMOS ANALOG SWITCH |
| | | | INCORPORATED | |
| 450 | U12 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 480 | U5 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 490 | U4 | LM393N | NATIONAL | VOLTAGE COMPARATOR |
| | | | SEMICONDUCTOR | |
| 495 | U10 | 74HC00 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 495 | U3 | 74HC74 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| FIG. 6 | | | | |
| 1010 | U24 | DG528CK | SILICONIX | OCTAL ANALOG SWITCH |
| | | | INCORPORATED | |
| 1020 | U25 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 1030 | U25 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 1040 | U38 | AD7524LN | ANALOG DEVICES | DAC |
| 1040 | U42 | 74HC374 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 1040 | U37 | LF442N | NATIONAL | LOW POWER OP AMP |
| | | | SEMICONDUCTOR | |
| 1050 | U36 | LF398N | NATIONAL | SAMPLE & HOLD OP AMP |
| | | | SEMICONDUCTOR | |
| 1060 | U29 | LM211P | TEXAS | LOW OFFSET VOLTAGE COMPARATOR |
| | | | INSTRUMENTS | |
| 1080 | U43 | AD7548KN | ANALOG DEVICES | CMOS 12-BIT DAC |
| 1080 | U31 | LF411ACN | NATIONAL | LOW OFFSET OP AMP |
| | | | SEMICONDUCTOR | |
| 1080 | U25 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 610 | U18 | DG528CK | SILICONIX | OCTAL ANALOG SWITCH |
| | | | INCORPORATED | |

| | | | | |
|--------|-----|---------------|-----------------|----------------------------|
| 620 | U11 | LF444 | NATIONAL | QUAD JFET OP AMP |
| 630 | U11 | LF444 | SEMICONDUCTOR | |
| | | | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| FIG. 7 | | | | |
| | U2 | 82C84A-2 | NEC | CMOS 8 MHZ CLOCK GENERATOR |
| | U1 | 74HC74 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U1 | 74HC74 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 2040 | U8 | MSM80C88RS-2 | OKI ELECTRIC | CPU 8MHZ, 125ns |
| | U3 | 74HC74 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U33 | 74HC374 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U9 | 74HC04 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U3 | 74HC74 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U9 | 74HC04 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U19 | 74HC00 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U9 | 74HC04 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 2030 | U21 | MBM27C512-25 | FUJITSU LIMITED | CMOS 64K X 8 ROM |
| 2020 | U15 | DS1242 | DALLAS | CMOS 32K X 8 RAM |
| | | | SEMICONDUCTOR | |
| | U23 | 74HC138 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U17 | 74HC138 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U19 | 74HC00 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U19 | 74HC00 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| | U16 | 82C51A | OKI ELECTRIC | CMOS UART |
| | U22 | MSM82C59A-2RS | OKI ELECTRIC | CMOS INTERRUPT CONTROLLER |
| 2050 | U34 | MSM82C53-2 | OKI ELECTRIC | CMOS TRIPLE TIMER |
| 2050 | U38 | MSM82C53-2 | OKI ELECTRIC | CMOS TRIPLE TIMER |
| 2050 | U9 | 74HC04 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 2050 | U39 | 74HC393 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 2050 | U35 | D2732A | INTEL | 4096 X 8 ROM |
| | | | CORPORATION | |
| 2050 | U40 | 74HC374 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| 2050 | U28 | 74HC374 | TEXAS | HIGH SPEED CMOS |
| | | | INSTRUMENTS | |
| FIG. 8 | | | | |
| 520 | U3 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |
| 530 | U2 | LF444 | NATIONAL | QUAD JFET OP AMP |
| | | | SEMICONDUCTOR | |

| | | | | |
|-----|----|--------|---------------------------|-----------------------------|
| 530 | U3 | LF444 | NATIONAL SEMICONDUCTOR | QUAD JFET OP AMP |
| 570 | U7 | LM311N | NATIONAL SEMICONDUCTOR | VOLTAGE COMPARATOR W/STROBE |

Claims

1. A method for calculating the concentration of a blood constituent from the blood flow characteristics of a patient by detecting an absorption signal corresponding to the absorption of light measured at two or more wavelengths in the patient's tissue including periodic changes in amplitude caused by periodic arterial pulses in the blood flow characteristics related to the patient's heartbeat and aperiodic changes in amplitude unrelated to the patient's heartbeat, characterized by, for each of the measured wavelengths:
 - obtaining a time-measure of the absorption signal including periodic information and aperiodic information;
 - processing the time-measure collectively to determine a composite waveform having relative maximum and minimum amplitudes corresponding to the periodic information in the time-measure, the composite waveform corresponding to a frequency domain transform of a complex data set derived from the time-measure; and thereafter calculating the concentration of the blood constituent from the relative maximum and minimum amplitudes of the composite periodic waveforms of the detected wavelengths.
2. The method of claim 1 characterized in that obtaining a time-measure of the absorption signal is further characterized by updating the time-measure with the occurrence of new heartbeats so that the time-measure and the determined composite waveform include periodic information related to the new heartbeats.
3. The method of claim 2 characterized in that obtaining a time-measure of the absorption signal is further characterized by obtaining a predetermined time-measure including a predetermined number of periodic information corresponding to the predetermined number of heartbeats.
4. The method of claim 3 characterized in that processing the collected time-measure is further characterized by Fourier transforming the collected time-measure into the frequency domain having spectral components corresponding to the frequency components of the collected time-measure, whereby the relative maximum amplitude corresponds to the amplitude at the spectral line for the predetermined number of heartbeats in the collected time-measure, and the relative minimum amplitude and the average background intensity amplitude correspond to the zero frequency spectral component.
5. The method of claim 4 characterized in that processing the collected time-measure is further characterized by identifying the amplitude at the spectral component corresponding to the predetermined number of heartbeats by detecting a significant spectral component amplitude at the frequency corresponding to an integral multiple of the predetermined number of heartbeats.
6. The method of claim 4 characterized in that processing the collected time-measure is further characterized by identifying the amplitude at the spectral component corresponding to the predetermined number of heartbeats by detecting the patient's heartrate and correlating the detected heartrate for the time-measure to the spectral components of the transformed time-measure.
7. The method of claims 2 to 6, characterized in that the absorption signal includes two wavelengths, further characterized in that collecting the time-measure is further characterized by converting the absorption signals for each of the wavelengths into digital data;
 - collecting a first predetermined number of digitized data points for each of the wavelengths of the absorption signal;
 - forming a complex data set wherein one of the wavelengths data correspond to the real component and the other of the wavelengths data correspond to the imaginary component;
 - determining the background absorption signal corresponding to the zero frequency component from the complex data set and subtracting the determined background absorption component from the complex data set, thereby forming a modified data set;

decimating the modified data set in time into a second predetermined number of samples;
 processing the second predetermined number of samples using a function selected from among the group
 comprising Hamming windows and similar artifact reduction window functions, thereby forming a processed data set;

Fourier transforming the processed data set into the frequency domain;

determining the spectral components of the first and second wavelengths at the fundamental frequency for
 the first predetermined number of heartbeats in the time sample from the transform; and

determining the relative maximum and minimum amplitudes for the first and second wavelengths using the
 amplitude of the zero frequency and fundamental frequency spectral components.

8. The method of claims 3 to 7 further characterized by determining the time of the occurrence of a heartbeat from
 the patient's ECG signal, and sampling the time-measure of the absorption signal to obtain a second predetermined
 number of samples per heartbeat, based on the determined time of occurrence of the heartbeats for each of the
 predetermined number of heartbeats in the time-measure.

9. An apparatus for calculating the concentration of a blood constituent from a photoelectrically detected absorption
 signal corresponding to the absorption of light measured at two or more wavelengths in a patient's tissue, including
 periodic changes in amplitude caused by periodic arterial pulses in the blood flow characteristics that are related
 to the patient's heartbeat, and including aperiodic changes in amplitude unrelated to the patient's heartbeat, and
 including a means (130) for receiving the photoelectrically detected absorption signals of each of the measured
 wavelengths characterized by:

means (200, 300, 400) for obtaining a time-measure of the detected absorption signals including periodic
 information and aperiodic information;

means (1000 to 1080) for processing the obtained time-measures collectively to determine a composite wave-
 form having relative maximum and minimum amplitudes corresponding to the periodic information in the time-meas-
 ure, the composite waveform corresponding to a frequency domain transform of a complex data set derived from
 the time-measure, and

means (2000) for calculating the concentration of the blood constituent from the relative maximum and min-
 imum amplitudes of the composite periodic wave forms of the detected wavelengths.

10. The apparatus of claim 9 characterized in that the means for obtaining a time-measure of the detected absorption
 signal is further characterized by means (220, 230, 250) for updating the time-measure with the occurrence of new
 heartbeats so that the time-measure and the determined composite waveform includes periodic information related
 to the new heartbeats.

11. The apparatus of claim 10 characterized in that the means for obtaining a time-measure of the detected absorption
 signal obtains a time-measure including the periodic information corresponding to a predetermined number of heart-
 beats.

12. The apparatus of claim 11 characterized in that the means for processing the collected time-measure is further
 characterized by means (Fig. 9) for Fourier transforming the collected time-measure into a frequency domain wave-
 form having spectral components corresponding to the frequency components of the collected time-measure,
 whereby the relative maximum amplitude corresponds to the amplitude at the spectral line for the predetermined
 number of heartbeats in the collected time-measure, and the relative minimum amplitude and the average back-
 ground intensity amplitude corresponds to the amplitude at the zero frequency spectral component.

13. The apparatus of claim 12 characterized in that the means for processing the collected time-measure detects the
 amplitude at the spectral component corresponding to the predetermined number of heartbeats by detecting a
 significant spectral component amplitude at a frequency that is about an integral multiple of the predetermined
 number of heartbeats.

14. The apparatus of claim 12 further characterized by means for detecting the heartrate of the patient, characterized
 in that the means for processing the collected time-measure detects the amplitude at the spectral component cor-
 responding to the predetermined number of heartbeats and the detected heartrate.

15. The apparatus of claims 10 to 14 characterized in that the absorption signal has two wavelengths, and the means
 for collecting the time-measure is further characterized by:

means (1060, 1080) for converting the analog absorption signals for each of the wavelengths into digital data;

means for collecting (1070) a first predetermined number of digitized data points for each of the wavelengths
 of the absorption signal;

first processor means (2000) for forming a complex data set wherein one of the wavelengths data correspond to the real component and the other of the wavelengths data correspond to the imaginary component;

second processor means for determining the background absorption signal corresponding to the zero frequency component from the complex data set and subtracting the determined background absorption component from the complex data set, thereby forming a modified data set;

means for decimating the modified data set in time into a second predetermined number of samples;

third processing means for processing the second predetermined number of samples using Hamming Window functions, thereby forming a processed data set;

means (Fig. 9) for Fourier transforming the processed data set into the frequency domain;

means for determining the spectral components of the first and second wavelengths at the fundamental frequency for the first predetermined number of heartbeats in the time sample from the transform; and

means for determining the relative maximum and minimum amplitudes for the first and second wavelengths using the amplitude of the zero frequency and fundamental frequency spectral components.

Patentansprüche

1. Verfahren zum Berechnen der Konzentration eines Blutbestandteils anhand der Blutflußmerkmale eines Patienten durch Detektieren eines der Absorption von Licht entsprechenden Absorptionssignals, die gemessen wird bei zwei oder mehr Wellenlängen in dem Gewebe des Patienten mit periodischen Änderungen der Amplitude, die durch periodische arterielle Pulse in den Blutflußmerkmalen in Beziehung zu dem Herzschlag des Patienten verursacht werden, und aperiodischen Änderungen der Amplitude ohne Beziehung zu dem Herzschlag des Patienten, gekennzeichnet für jede der gemessenen Wellenlängen durch:

Erhalten eines Zeitmaßes des Absorptionssignals mit periodischen Informationen und aperiodischen Informationen; kollektives Verarbeiten des Zeitmaßes, um eine zusammengesetzte Wellenform mit einer den periodischen Informationen in dem Zeitmaß entsprechenden relativen Maximum- und Minimumamplitude zu bestimmen, wobei die zusammengesetzte Wellenform einer Frequenzdomänen-Transformation eines komplexen Datensatzes entspricht, der aus dem Zeitmaß abgeleitet ist; und anschließendes Berechnen der Konzentration des Blutbestandteils anhand der relativen Maximum- und Minimumamplitude der zusammengesetzten periodischen Wellenformen der detektierten Wellenlängen.

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß das Erhalten eines Zeitmaßes des Absorptionssignals ferner gekennzeichnet ist durch Aktualisieren des Zeitmaßes mit dem Auftreten neuer Herzschläge, so daß das Zeitmaß und die bestimmte Zusammengesetzte Wellenform periodische Informationen in Beziehung zu den neuen Herzschlägen aufweisen.

3. Verfahren nach Anspruch 2, dadurch gekennzeichnet, daß das Erhalten eines Zeitmaßes des Absorptionssignals ferner gekennzeichnet ist durch Erhalten eines vorbestimmten Zeitmaßes mit einer der vorbestimmten Anzahl von Herzschlägen entsprechenden vorbestimmten Anzahl periodischer Informationen.

4. Verfahren nach Anspruch 3, dadurch gekennzeichnet, daß das Verarbeiten des erfaßten Zeitmaßes ferner gekennzeichnet ist durch Fourier-Transformieren des erfaßten Zeitmaßes in die Frequenzdomäne mit den Frequenzkomponenten des erfaßten Zeitmaßes entsprechenden Spektralanteilen, wodurch die relative Maximumamplitude der Amplitude an der Spektrallinie für die vorbestimmte Anzahl von Herzschlägen in dem erfaßten Zeitmaß entspricht und die relative Minimumamplitude sowie die Amplitude der mittleren Hintergrundintensität dem Spektralgleichanteil entsprechen.

5. Verfahren nach Anspruch 4, dadurch gekennzeichnet, daß das Verarbeiten des erfaßten Zeitmaßes ferner gekennzeichnet ist durch Identifizieren der Amplitude bei dem der vorbestimmten Anzahl von Herzschlägen entsprechenden Spektralanteil durch Detektieren einer signifikanten Spektralanteilamplitude bei der einem ganzzahligen Vielfachen der vorbestimmten Anzahl von Herzschlägen entsprechenden Frequenz.

6. Verfahren nach Anspruch 4, dadurch gekennzeichnet, daß das Verarbeiten des erfaßten Zeitmaßes ferner gekennzeichnet ist durch Identifizieren der Amplitude bei dem der vorbestimmten Anzahl von Herzschlägen entsprechenden Spektralanteil durch Detektieren der Herzfrequenz des Patienten und Korrelieren der detektierten Herzfrequenz für das Zeitmaß mit den Spektralanteilen des transformierten Zeitmaßes.

7. Verfahren nach Anspruch 2 bis 6, dadurch gekennzeichnet, daß das Absorptionssignal zwei Wellenlängen aufweist, ferner dadurch gekennzeichnet, daß das Erfassen des Zeitmaßes ferner gekennzeichnet ist durch: Umwandeln der Absorptionssignale für jede der Wellenlängen in digitale Daten;

Erfassen einer ersten vorbestimmten Anzahl digitalisierter Datenpunkte für jede der Wellenlängen des Absorptionssignals;

Bilden eines komplexen Datensatzes, in dem ein Teil der Wellenlängendaten dem reellen Anteil entspricht und der andere Teil der Wellenlängendaten dem imaginären Anteil entspricht;

Bestimmen des dem Gleichanteil entsprechenden Hintergrundabsorptionssignals anhand des komplexen Datensatzes und Subtrahieren des bestimmten Hintergrundabsorptionsanteils von dem komplexen Datensatz, wodurch ein modifizierter Datensatz gebildet wird;

zeitliches Dezimieren des modifizierten Datensatzes zu einer zweiten vorbestimmten Anzahl von Abtastungen;

Verarbeiten der zweiten vorbestimmten Anzahl von Abtastungen unter Verwendung einer Funktion, die aus der Gruppe ausgewählt ist, die Hamming-Fenster- und ähnliche Fensterfunktionen zur Artefaktreduzierung aufweist, wodurch ein verarbeiteter Datensatz gebildet wird;

Fourier-Transformieren des verarbeiteten Datensatzes in die Frequenzdomäne;

Bestimmen der Spektralanteile der ersten und zweiten Wellenlänge bei der Grundfrequenz für die erste vorbestimmte Anzahl von Herzschlägen in der Zeitabtastung anhand der Transformation; und

Bestimmen der relativen Maximum- und Minimumamplitude für die erste und zweite Wellenlänge unter Verwendung der Amplitude des Gleich- und Grundfrequenzspektralanteils.

8. Verfahren nach Anspruch 3 bis 7, ferner gekennzeichnet durch Bestimmen der Zeit des Auftretens eines Herzschlags anhand des EKG-Signals des Patienten und Abtasten des Zeitmaßes des Absorptionssignals, um eine zweite vorbestimmte Anzahl von Abtastungen je Herzschlag auf der Grundlage der bestimmten Zeit des Auftretens der Herzschläge für jeden der vorbestimmten Anzahl von Herzschlägen in dem Zeitmaß zu erhalten.

9. Gerät zum Berechnen der Konzentration eines Blutbestandteils anhand eines der Absorption von Licht entsprechenden fotoelektrisch detektierten Absorptionssignals, die gemessen wird bei zwei oder mehr Wellenlängen in einem Gewebe eines Patienten mit periodischen Änderungen der Amplitude, die durch periodische arterielle Pulse in den Blutflußmerkmalen in Beziehung zu dem Herzschlag des Patienten verursacht werden, und mit aperiodischen Änderungen der Amplitude ohne Beziehung zu dem Herzschlag des Patienten und mit einer Einrichtung (130) zum Empfangen der fotoelektrisch detektierten Absorptionssignale jeder der gemessenen Wellenlängen, gekennzeichnet durch:

eine Einrichtung (200, 300, 400) zum Erhalten eines Zeitmaßes der detektierten Absorptionssignale mit periodischen Informationen und aperiodischen Informationen; eine Einrichtung (1000 bis 1080) zum kollektiven Verarbeiten des erhaltenen Zeitmaßes, um eine zusammengesetzte Wellenform mit einer den periodischen Informationen in dem Zeitmaß entsprechenden relativen Maximum- und Minimumamplitude zu bestimmen, wobei die zusammengesetzte Wellenform einer Frequenzdomänen-Transformation eines komplexen Datensatzes entspricht, der aus dem Zeitmaß abgeleitet ist; und

eine Einrichtung (2000) zum Berechnen der Konzentration des Blutbestandteils anhand der relativen Maximum- und Minimumamplitude der zusammengesetzten periodischen Wellenformen der detektierten Wellenlängen.

10. Gerät nach Anspruch 9, dadurch gekennzeichnet, daß die Einrichtung zum Erhalten eines Zeitmaßes des detektierten Absorptionssignals ferner gekennzeichnet ist durch eine Einrichtung (220, 230, 250) zum Aktualisieren des Zeitmaßes mit dem Auftreten neuer Herzschläge, so daß das Zeitmaß und die bestimmte zusammengesetzte Wellenform periodische Informationen in Beziehung zu den neuen Herzschlägen aufweisen.

11. Gerät nach Anspruch 10, dadurch gekennzeichnet, daß die Einrichtung zum Erhalten eines Zeitmaßes des detektierten Absorptionssignals ein Zeitmaß mit den einer vorbestimmten Anzahl von Herzschlägen entsprechenden periodischen Informationen erhält.

12. Gerät nach Anspruch 11, dadurch gekennzeichnet, daß die Einrichtung zum Verarbeiten des erfaßten Zeitmaßes ferner gekennzeichnet ist durch eine Einrichtung (Fig. 9) zum Fourier-Transformieren des erfaßten Zeitmaßes in eine Frequenzdomänen-Wellenform mit den Frequenzkomponenten des erfaßten Zeitmaßes entsprechenden Spektralanteilen, wodurch die relative Maximumamplitude der Amplitude an der Spektrallinie für die vorbestimmte Anzahl von Herzschlägen in dem erfaßten Zeitmaß entspricht und die relative Minimumamplitude sowie die Amplitude der mittleren Hintergrundintensität dem Spektralgleichanteil entsprechen.

13. Gerät nach Anspruch 12, dadurch gekennzeichnet, daß die Einrichtung zum Verarbeiten des erfaßten Zeitmaßes die Amplitude bei dem der vorbestimmten Anzahl von Herzschlägen entsprechenden Spektralanteil durch Detektieren einer signifikanten Spektralanteilamplitude bei einer Frequenz detektiert, die etwa ein ganzzahliges Vielfaches der vorbestimmten Anzahl von Herzschlägen beträgt.

14. Gerät nach Anspruch 12, ferner gekennzeichnet durch eine Einrichtung zum Detektieren der Herzfrequenz des Patienten, dadurch gekennzeichnet, daß die Einrichtung zum Verarbeiten des erfaßten Zeitmaßes die Amplitude bei dem der vorbestimmten Anzahl von Herzschlägen und der detektierten Herzfrequenz entsprechenden Spektralanteil detektiert.
15. Gerät nach Anspruch 10 bis 14, dadurch gekennzeichnet, daß das Absorptionssignal zwei Wellenlängen hat und die Einrichtung zum Erfassen des Zeitmaßes ferner gekennzeichnet ist durch:
 - eine Einrichtung (1060, 1080) zum Umwandeln der analogen Absorptionssignale für jede der Wellenlängen in digitale Daten;
 - eine Einrichtung (1070) zum Erfassen einer ersten vorbestimmten Anzahl digitalisierter Datenpunkte für jede der Wellenlängen des Absorptionssignals;
 - eine erste Prozesseinrichtung (2000) zum Bilden eines komplexen Datensatzes, in dem ein Teil der Wellenlängendaten dem reellen Anteil entspricht und der andere Teil der Wellenlängendaten dem imaginären Anteil entspricht;
 - eine zweite Prozesseinrichtung zum Bestimmen des dem Gleichanteil entsprechenden Hintergrundabsorptionssignals anhand des komplexen Datensatzes und Subtrahieren des bestimmten Hintergrundabsorptionsanteils von dem komplexen Datensatz, wodurch ein modifizierter Datensatz gebildet wird;
 - eine Einrichtung zum zeitlichen Dezimieren des modifizierten Datensatzes zu einer zweiten vorbestimmten Anzahl von Abtastungen;
 - eine dritte Verarbeitungseinrichtung zum Verarbeiten der zweiten vorbestimmten Anzahl von Abtastungen unter Verwendung von Hamming-Fensterfunktionen, wodurch ein verarbeiteter Datensatz gebildet wird;
 - eine Einrichtung (Fig. 9) zum Fourier-Transformieren des verarbeiteten Datensatzes in die Frequenzdomäne;
 - eine Einrichtung zum Bestimmen der Spektralanteile der ersten und zweiten Wellenlänge bei der Grundfrequenz für die erste vorbestimmte Anzahl von Herzschlägen in der Zeitabtastung anhand der Transformation; und
 - eine Einrichtung zum Bestimmen der relativen Maximum- und Minimumamplitude für die erste und zweite Wellenlänge unter Verwendung der Amplitude des Gleich- und Grundfrequenzspektralanteils.

Revendications

1. Procédé de calcul de la concentration d'un élément constituant du sang à partir des caractéristiques d'écoulement du sang d'un patient, par détection d'un signal d'absorption correspondant à l'absorption de la lumière mesurée à au moins deux longueurs d'onde dans un tissu du patient, le signal comprenant des changements périodiques d'amplitude provoqués par les impulsions artérielles périodiques des caractéristiques d'écoulement du sang par rapport aux pulsations cardiaques du patient et des changements apériodiques d'amplitude qui ne sont pas liés à la pulsation cardiaque du patient, caractérisé, pour chaque longueur d'onde mesurée, par
 - l'obtention d'une mesure temporelle du signal d'absorption contenant l'information périodique et l'information apériodique,
 - le traitement collectif de la mesure temporelle pour la détermination d'une forme d'onde composite ayant des amplitudes maximale et minimale relatives correspondant à l'information périodique de la mesure temporelle, la forme d'onde composite correspondant à une transformée en domaine de fréquences d'un ensemble de données complexes dérivé de la mesure temporelle, puis
 - le calcul de la concentration de l'élément constituant du sang à partir des amplitudes relatives maximale et minimale des formes d'onde périodiques composites des longueurs d'onde détectées.
2. Procédé selon la revendication 1, caractérisé en ce que l'obtention de la mesure temporelle du signal d'absorption est en outre caractérisée par la remise à jour de la mesure temporelle lors de l'apparition de nouvelles pulsations cardiaques afin que la mesure temporelle et la forme d'onde composite déterminée comprennent l'information périodique relative aux nouvelles pulsations cardiaques.
3. Procédé selon la revendication 2, caractérisé en ce que l'obtention d'une mesure temporelle du signal d'absorption est en outre caractérisée par l'obtention d'une mesure temporelle prédéterminée contenant un nombre prédéterminé d'informations périodiques correspondant au nombre prédéterminé de pulsations cardiaques.
4. Procédé selon la revendication 3, caractérisé en ce que le traitement de la mesure temporelle collectée est en outre caractérisé par une transformation de Fourier de la mesure temporelle collectée dans le domaine de fréquences, ayant les composantes spectrales correspondant aux composantes de fréquences de la mesure temporelle collectée, si bien que l'amplitude maximale relative correspond à l'amplitude dans la raie spectrale pour le nombre prédéterminé de pulsations cardiaques de la mesure temporelle collectée, et l'amplitude minimale relative et l'amplitude moyenne d'intensité du fond continu correspondent à la composante spectrale de fréquence nulle.

5. Procédé selon la revendication 4, caractérisé en ce que le traitement de la mesure temporelle collectée est en outre caractérisé par l'identification de l'amplitude à la composante spectrale correspondant au nombre prédéterminé de pulsations cardiaques par détection d'une amplitude significative de la composante spectrale à la fréquence correspondant à un multiple entier du nombre prédéterminé de pulsations cardiaques.
6. Procédé selon la revendication 4, caractérisé en ce que le traitement de la mesure temporelle collectée est en outre caractérisé par l'identification de l'amplitude à la composante spectrale correspondant au nombre prédéterminé de pulsations cardiaques par détection de la fréquence cardiaque du patient et corrélation de la fréquence cardiaque détectée pour la mesure temporelle aux composantes spectrales de la mesure temporelle transformée.
7. Procédé selon les revendications 2 à 6, caractérisé en ce que le signal d'absorption comporte deux longueurs d'onde, et caractérisé en outre en ce que la collecte de la mesure temporelle est caractérisée en outre par
 - la conversion des signaux d'absorption pour chacune des longueurs d'onde en données numériques,
 - la collecte d'un premier nombre prédéterminé de points de données numérisées pour chacune des longueurs d'onde du signal d'absorption,
 - la formation d'un ensemble de données complexes dans lequel les données de l'une des longueurs d'onde correspondent à la composante réelle et les données de l'autre des longueurs d'onde correspondent à la composante imaginaire,
 - la détermination du signal d'absorption du fond continu correspondant à la composante de fréquence nulle à partir de l'ensemble de données complexes, et la soustraction de la composante d'absorption du fond continu ainsi déterminée de l'ensemble de données complexes pour la formation d'un ensemble de données modifiées,
 - la décimation de l'ensemble modifié de données dans le temps en un second nombre prédéterminé d'échantillons,
 - le traitement du second nombre prédéterminé d'échantillons par une fonction choisie dans le groupe comprenant les fenêtres de Hamming et les fonctions analogues à fenêtre de réduction d'anomalies, pour la formation d'un ensemble traité de données,
 - la transformation de Fourier de l'ensemble de données traitées dans le domaine de fréquences,
 - la détermination des composantes spectrales à la première et à la seconde longueur d'onde à la fréquence fondamentale pour le premier nombre prédéterminé de pulsations cardiaques dans l'échantillon temporel tiré de la transformée, et
 - la détermination des amplitudes relatives maximale et minimale pour la première et la seconde longueur d'onde à l'aide de l'amplitude des composantes spectrales de fréquence nulle et de fréquence fondamentale.
8. Procédé selon les revendications 3 à 7, caractérisé en outre par la détermination du moment de l'apparition d'une pulsation cardiaque à partir du signal ECG du patient, et par l'échantillonnage de la mesure temporelle du signal d'absorption pour l'obtention d'un second nombre prédéterminé d'échantillons par pulsation cardiaque, d'après le temps déterminé d'apparition des pulsations cardiaques pour chacune des pulsations d'un nombre prédéterminé de pulsations cardiaques au cours de la mesure temporelle.
9. Appareil de calcul de la concentration d'un élément constituant du sang, à partir d'un signal d'absorption détecté photoélectriquement, correspondant à l'absorption de lumière mesurée à au moins deux longueurs d'onde dans un tissu d'un patient, comprenant des changements périodiques d'amplitude provoqués par des impulsions artérielles périodiques des caractéristiques d'écoulement du sang qui sont liés à la pulsation cardiaque du patient, et comprenant des changements apériodiques d'amplitude qui ne sont pas liés à la pulsation cardiaque du patient, et comportant un dispositif (130) destiné à recevoir les signaux d'absorption détectés photoélectriquement à chacune des longueurs d'onde mesurées, caractérisé par :
 - un dispositif (200, 300, 400) destiné à l'obtention d'une mesure temporelle des signaux d'absorption détectés contenant l'information périodique et l'information apériodique,
 - un dispositif (1000 à 1080) de traitement des mesures temporelles obtenues collectivement pour la détermination d'une forme d'onde composite ayant des amplitudes relatives maximale et minimale correspondant à l'information périodique au cours de la mesure temporelle, la forme d'onde composite correspondant à la transformée dans un domaine de fréquences d'un ensemble de données complexes dérivé de la mesure temporelle, et
 - un dispositif (2000) de calcul de la concentration de l'élément constituant du sang d'après les amplitudes relatives maximale et minimale des formes d'onde périodiques composites aux longueurs d'onde détectées.
10. Appareil selon la revendication 9, caractérisé en ce que le dispositif d'obtention d'une mesure temporelle du signal d'absorption détecté est en outre caractérisé par un dispositif (220, 230, 250) de remise à jour de la mesure temporelle lors de l'apparition de nouvelles pulsations cardiaques afin que la mesure temporelle et la forme d'onde composite déterminée comprennent l'information périodique liée aux nouvelles pulsations cardiaques.

11. Appareil selon la revendication 10, caractérisé en ce que le dispositif d'obtention d'une mesure temporelle du signal d'absorption détecté tire une mesure temporelle contenant l'information périodique correspondant à un nombre prédéterminé de pulsations cardiaques.

12. Appareil selon la revendication 11, caractérisé en ce que le dispositif de traitement de la mesure temporelle collectée est en outre caractérisé par un dispositif (figure 9) de transformation de Fourier de la mesure temporelle collectée en une forme d'onde dans le domaine de fréquences ayant des composantes spectrales correspondant aux composantes de fréquences d'une mesure temporelle collectée, si bien que l'amplitude maximale relative correspond à l'amplitude à la raie spectrale pour le nombre prédéterminé de pulsations cardiaques de la mesure temporelle collectée, et l'amplitude minimale relative et l'amplitude moyenne d'intensité du fond continu correspondent à l'amplitude de la composante spectrale à fréquence nulle.

13. Appareil selon la revendication 12, caractérisé en ce que le dispositif de traitement de la mesure temporelle collectée détecte l'amplitude de la composante spectrale correspondant au nombre prédéterminé de pulsations cardiaques par détection d'une amplitude significative de composante spectrale à une fréquence qui est de l'ordre d'un multiple entier du nombre prédéterminé de pulsations cardiaques.

14. Appareil selon la revendication 12, caractérisé en outre par un dispositif de détection de la fréquence cardiaque du patient, caractérisé en ce que le dispositif de traitement de la mesure temporelle collectée détecte l'amplitude de la composante spectrale correspondant au nombre prédéterminé de pulsations cardiaques et à la fréquence cardiaque détectée.

15. Appareil selon les revendications 10 à 14, caractérisé en ce que le signal d'absorption a deux longueurs d'onde, et le dispositif de collecte de la mesure temporelle est en outre caractérisé par :

un dispositif (1060, 1080) destiné à transformer les signaux analogiques d'absorption pour chacune des fréquences en données numériques,

un dispositif (1070) destiné à collecter un premier nombre prédéterminé de points numérisés de données pour chacune des longueurs d'onde du signal d'absorption,

un premier dispositif processeur (2000) destiné à former un ensemble de données complexes, les données à l'une des longueurs d'onde correspondant à la composante réelle et les données à l'autre des longueurs d'onde correspondant à la composante imaginaire,

un second dispositif processeur destiné à déterminer le signal d'absorption de fond continu correspondant à la composante de fréquence nulle à partir de l'ensemble de données complexes, et à soustraire la composante déterminée d'absorption du fond continu de l'ensemble de données complexes, avec formation d'un ensemble de données modifiées,

un dispositif de décimation de l'ensemble de données modifiées dans le temps en un second nombre prédéterminé d'échantillons,

un troisième dispositif de traitement du second nombre prédéterminé d'échantillons à l'aide de fonctions à fenêtre de Hamming pour la formation d'un ensemble de données traitées,

un dispositif (figure 9) de transformation de Fourier de l'ensemble de données traitées dans le domaine de fréquences,

un dispositif de détermination des composantes spectrales à la première et à la seconde longueur d'onde à la fréquence fondamentale pour le premier nombre prédéterminé de pulsations cardiaques dans le même échantillon temporel que la transformation, et

un dispositif destiné à déterminer les amplitudes relatives maximale et minimale à la première et à la seconde longueur d'onde à l'aide de l'amplitude des composantes spectrales à la fréquence nulle et à la fréquence fondamentale.

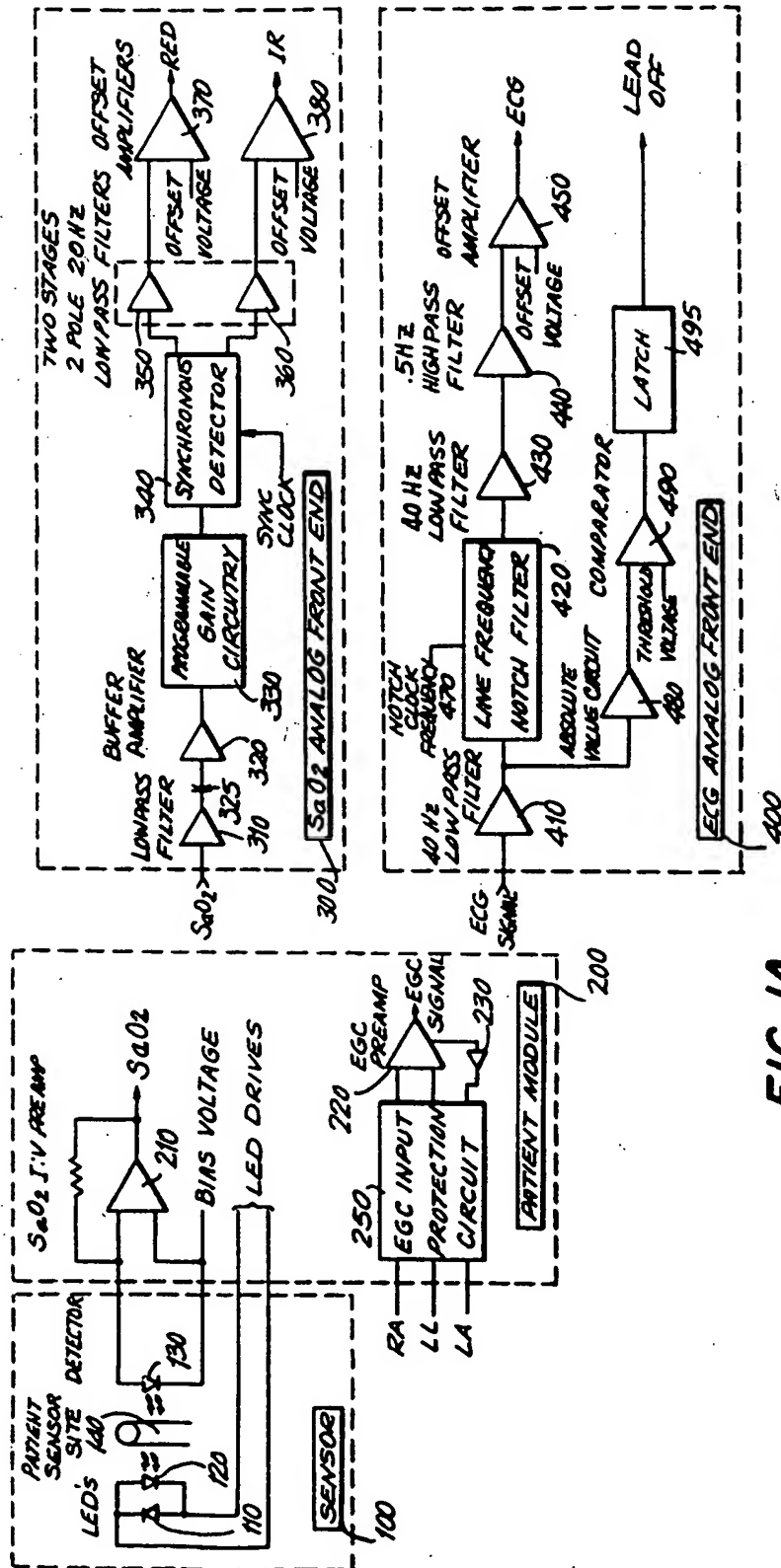


FIG. 1A

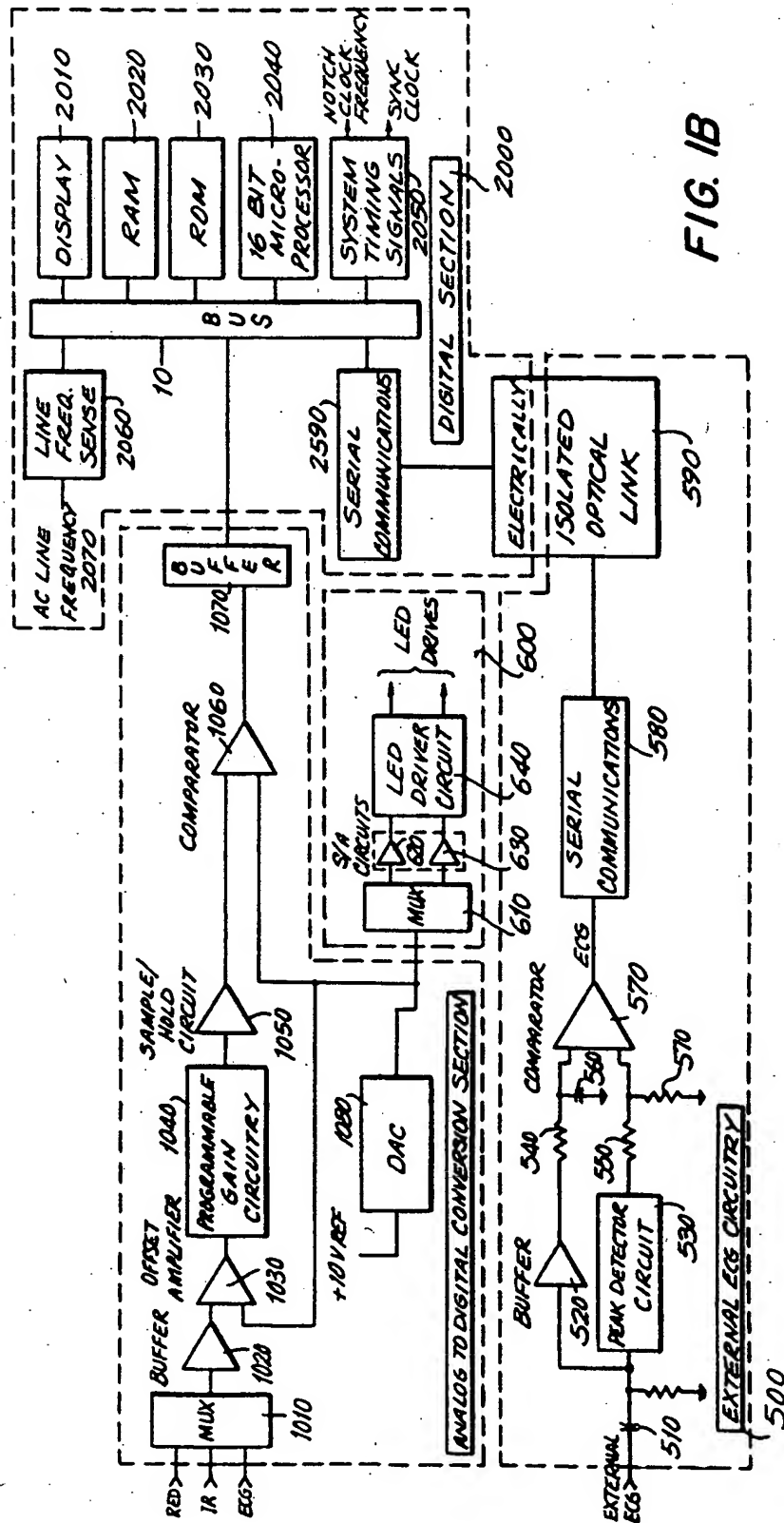


FIG. 1B

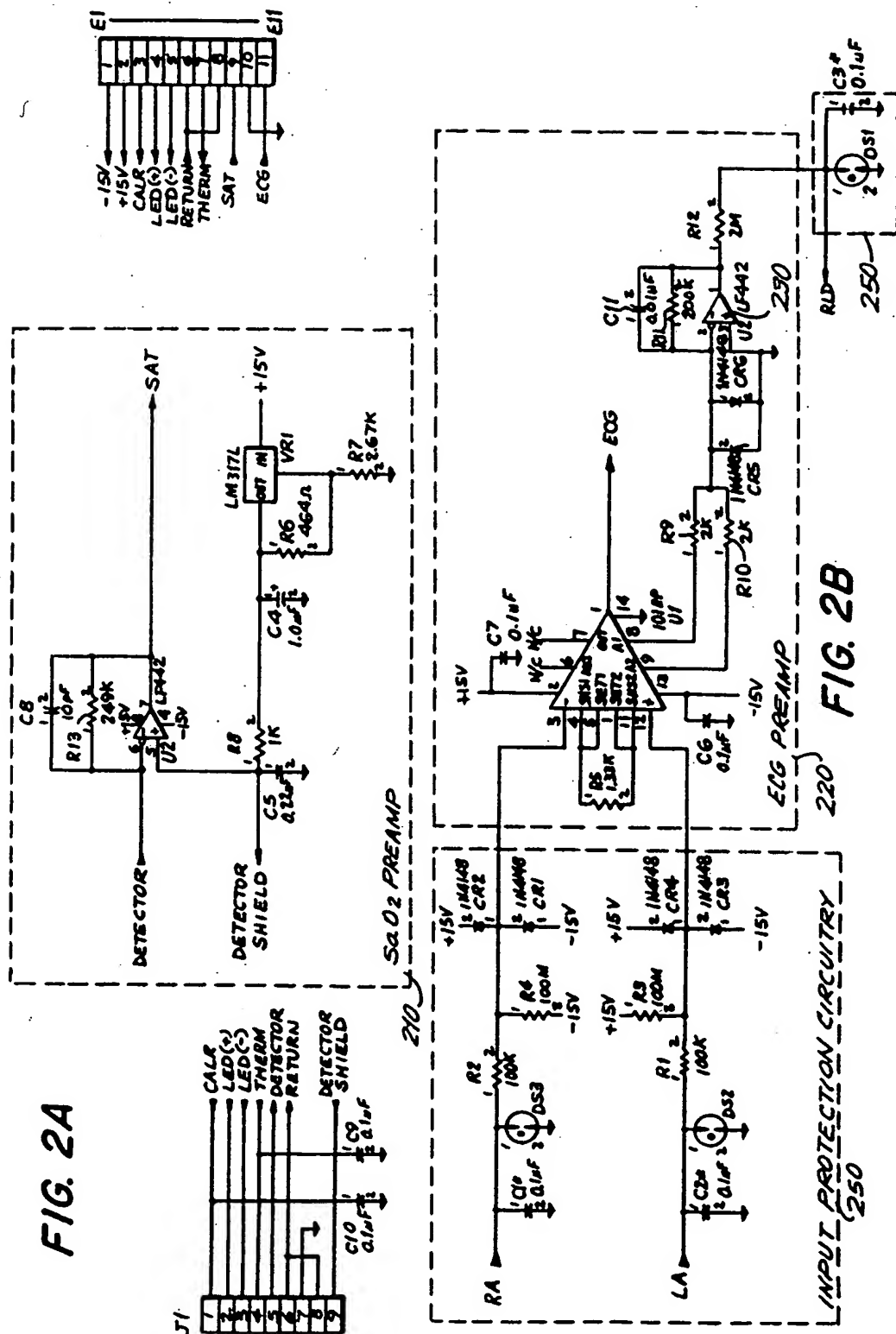


FIG. 3A

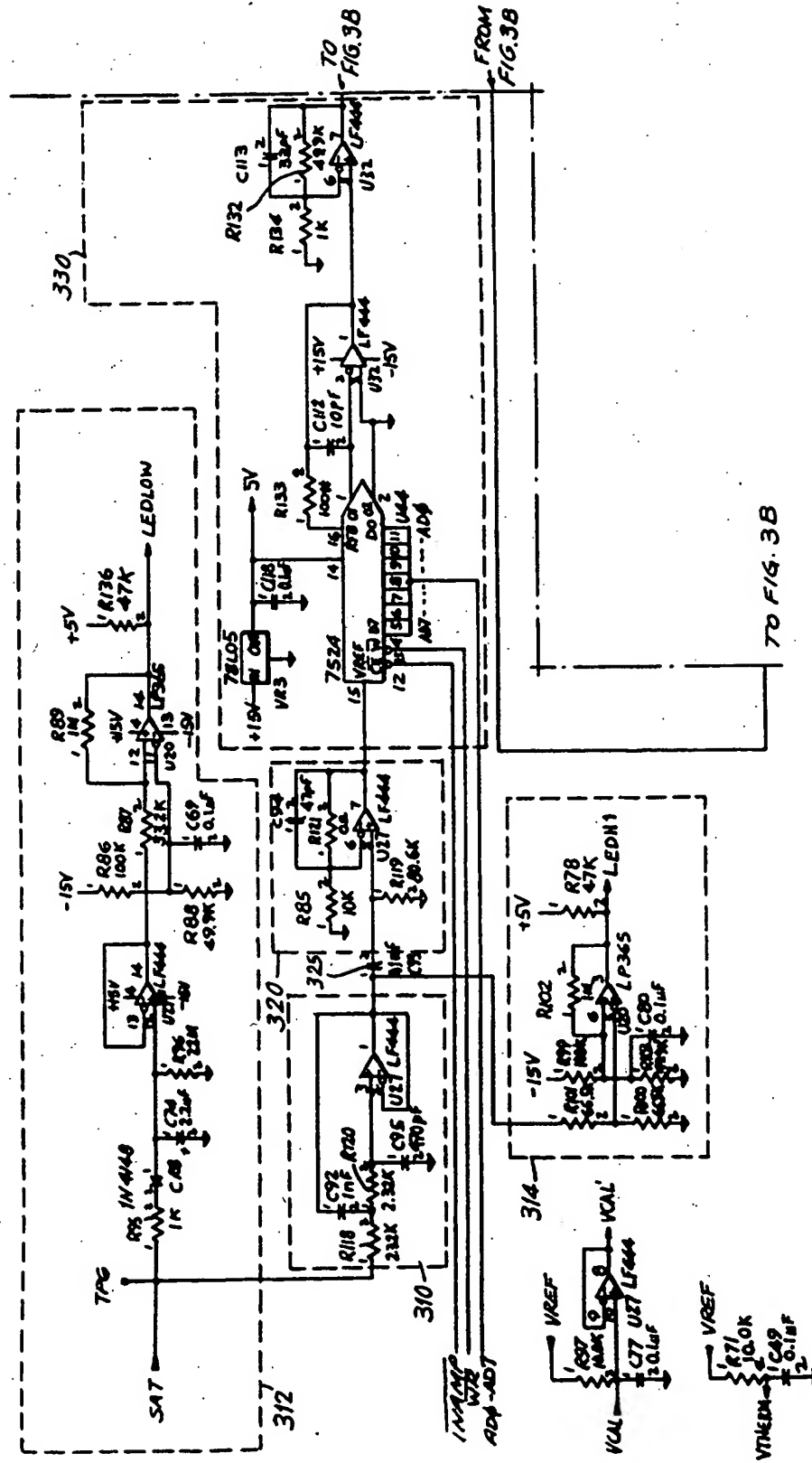


FIG. 3B

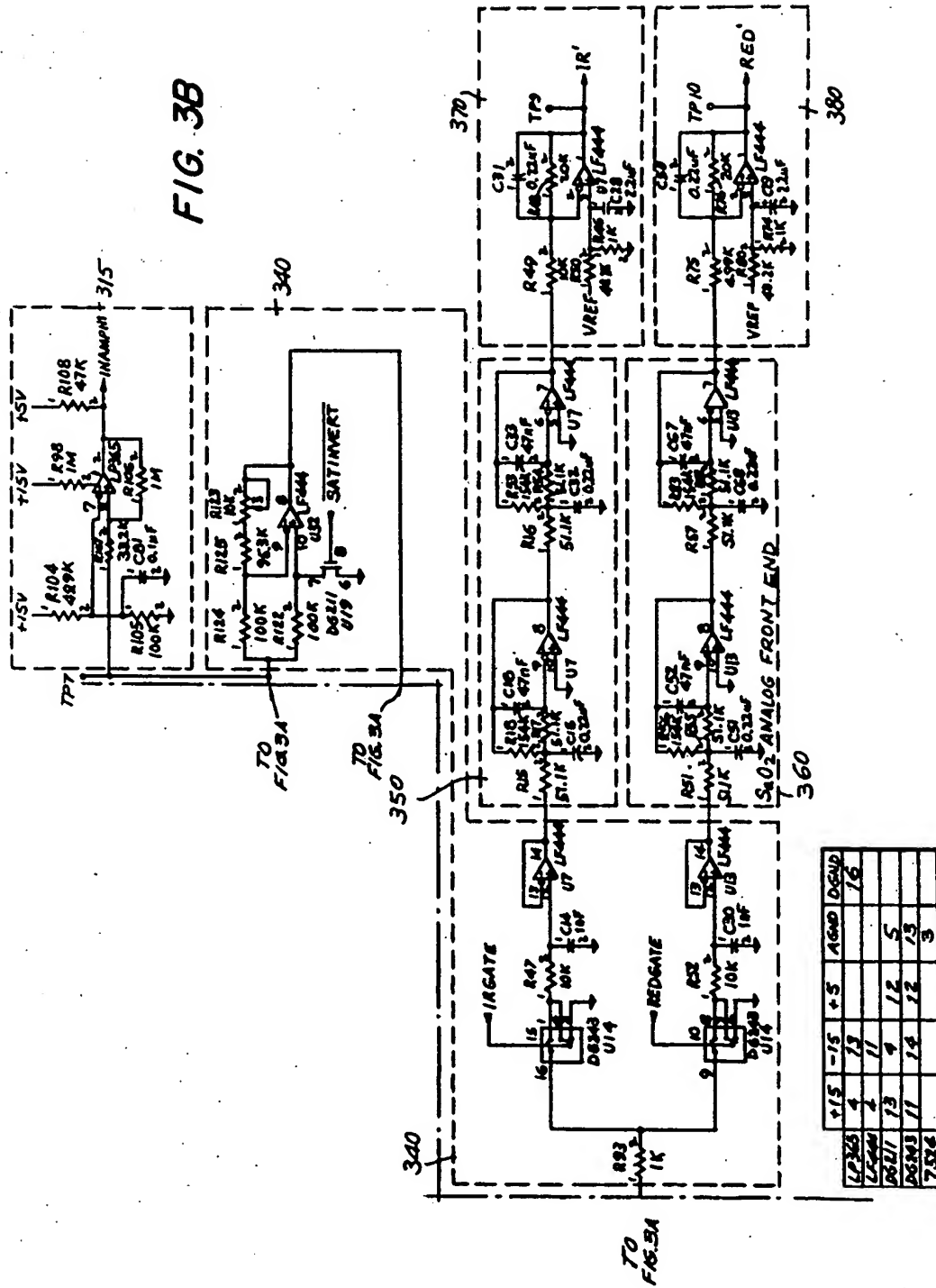


FIG. 4

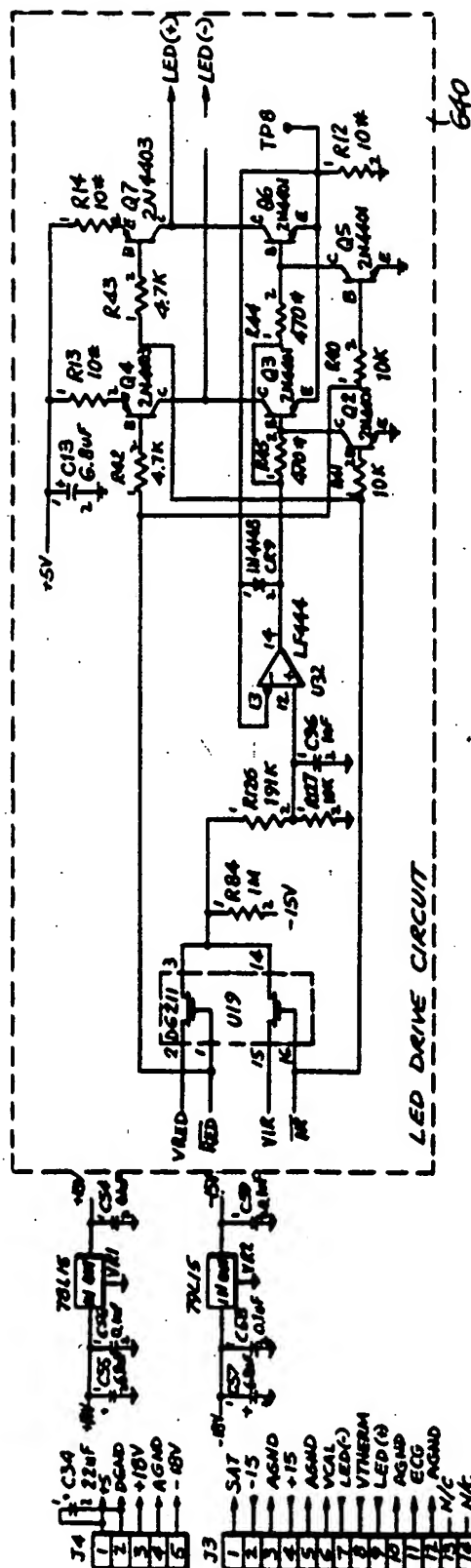
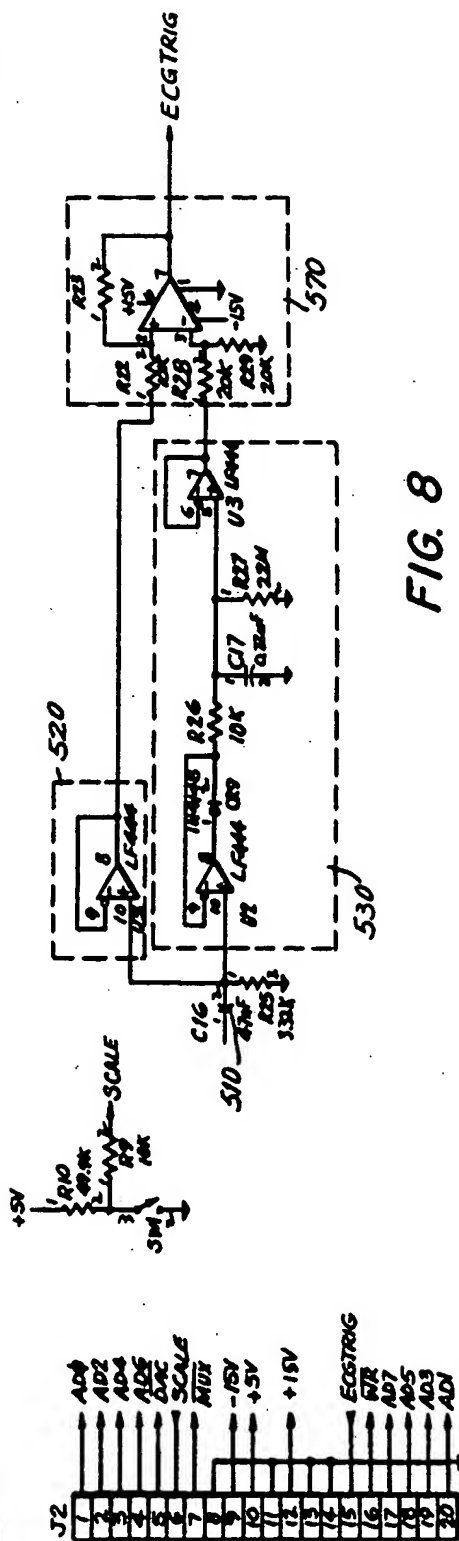


FIG. 8



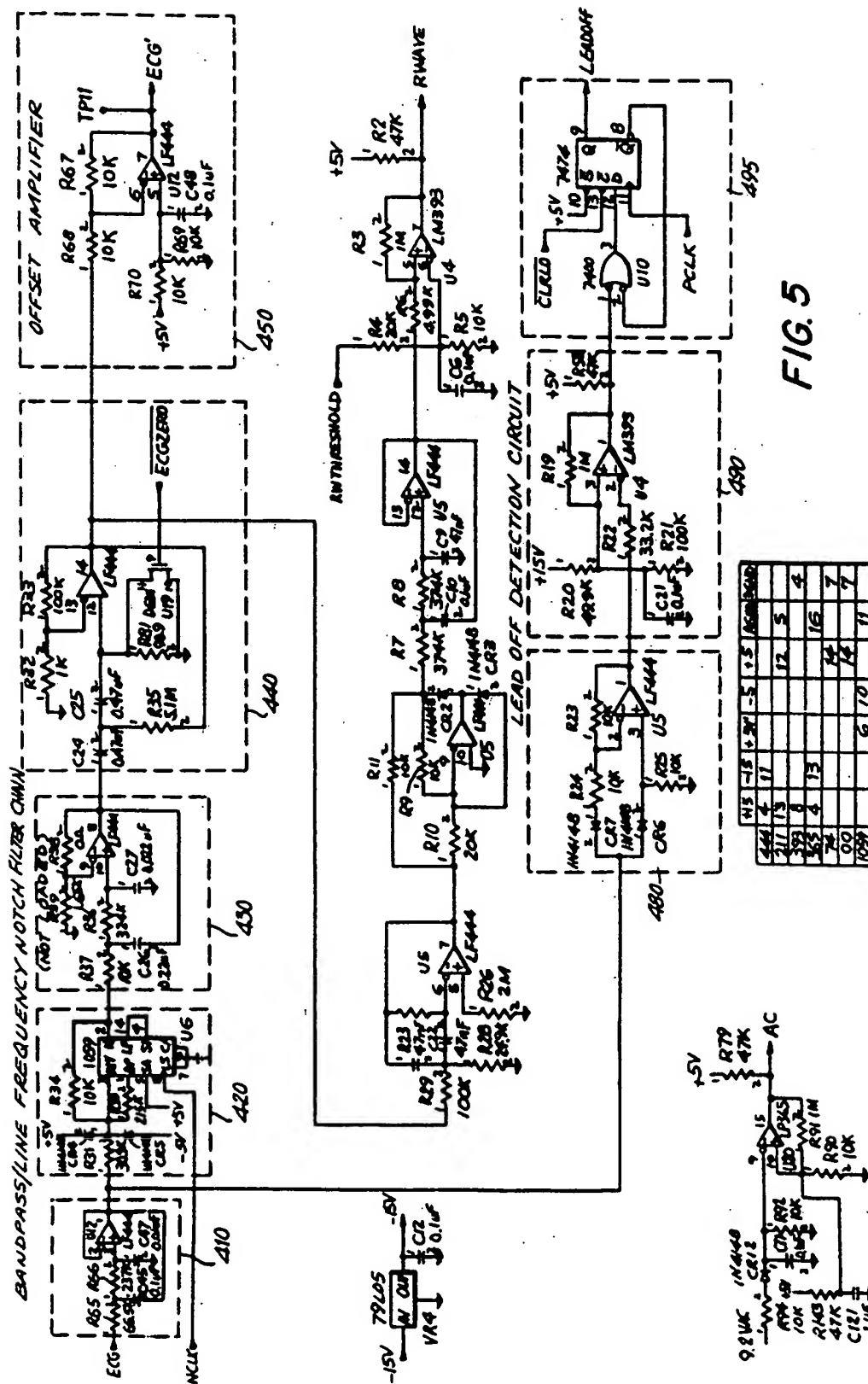
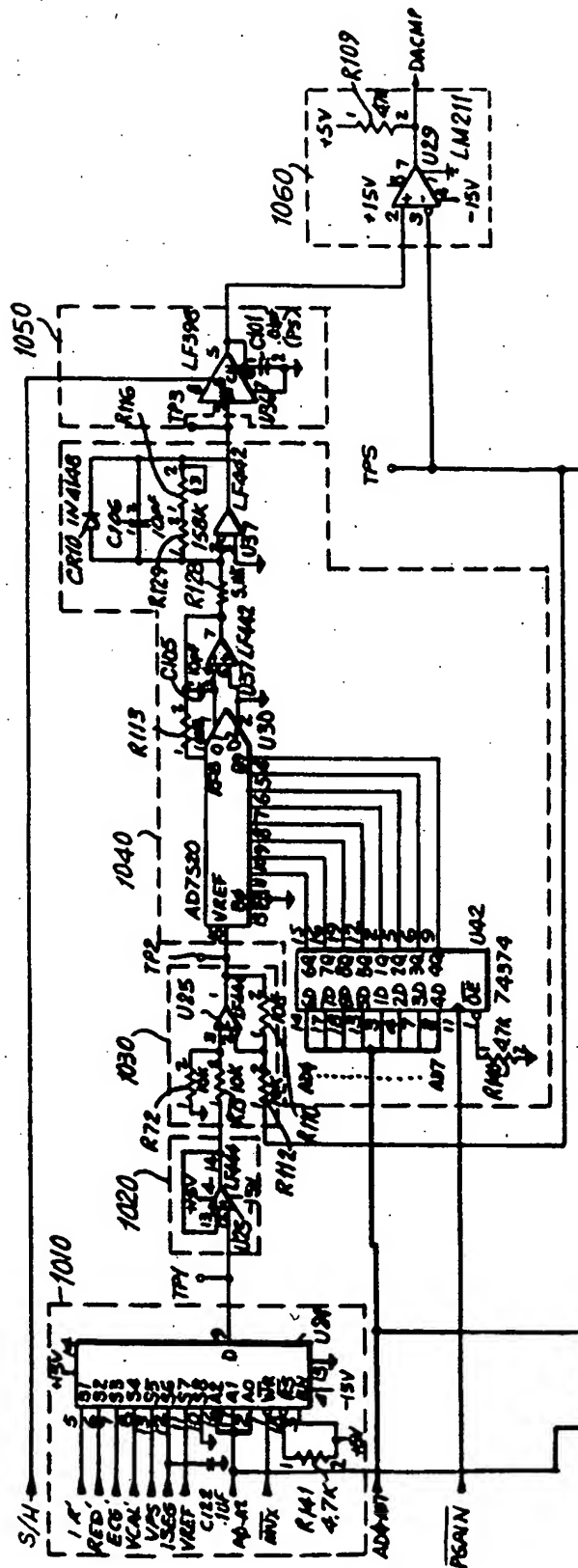


FIG. 5

FIG. 6A



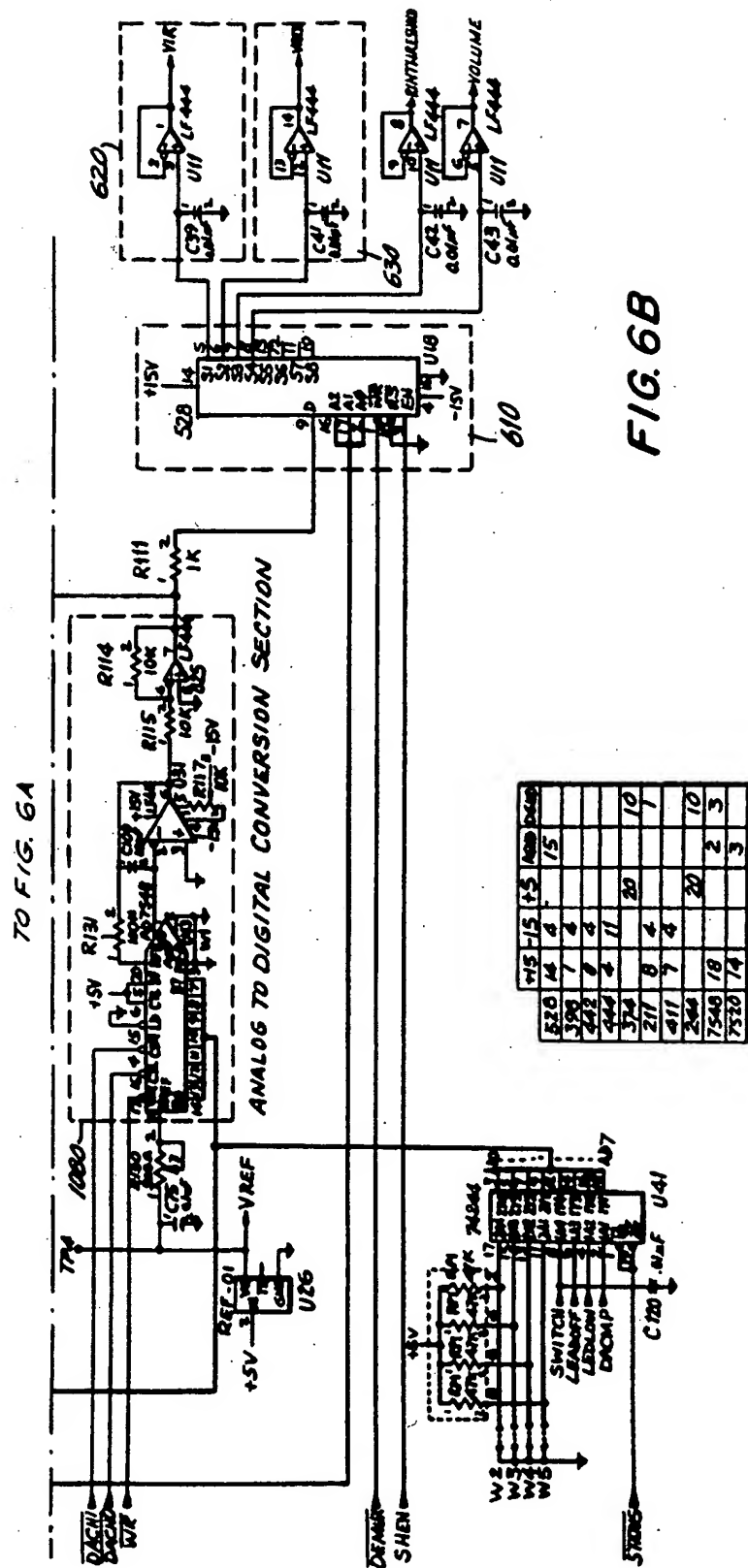
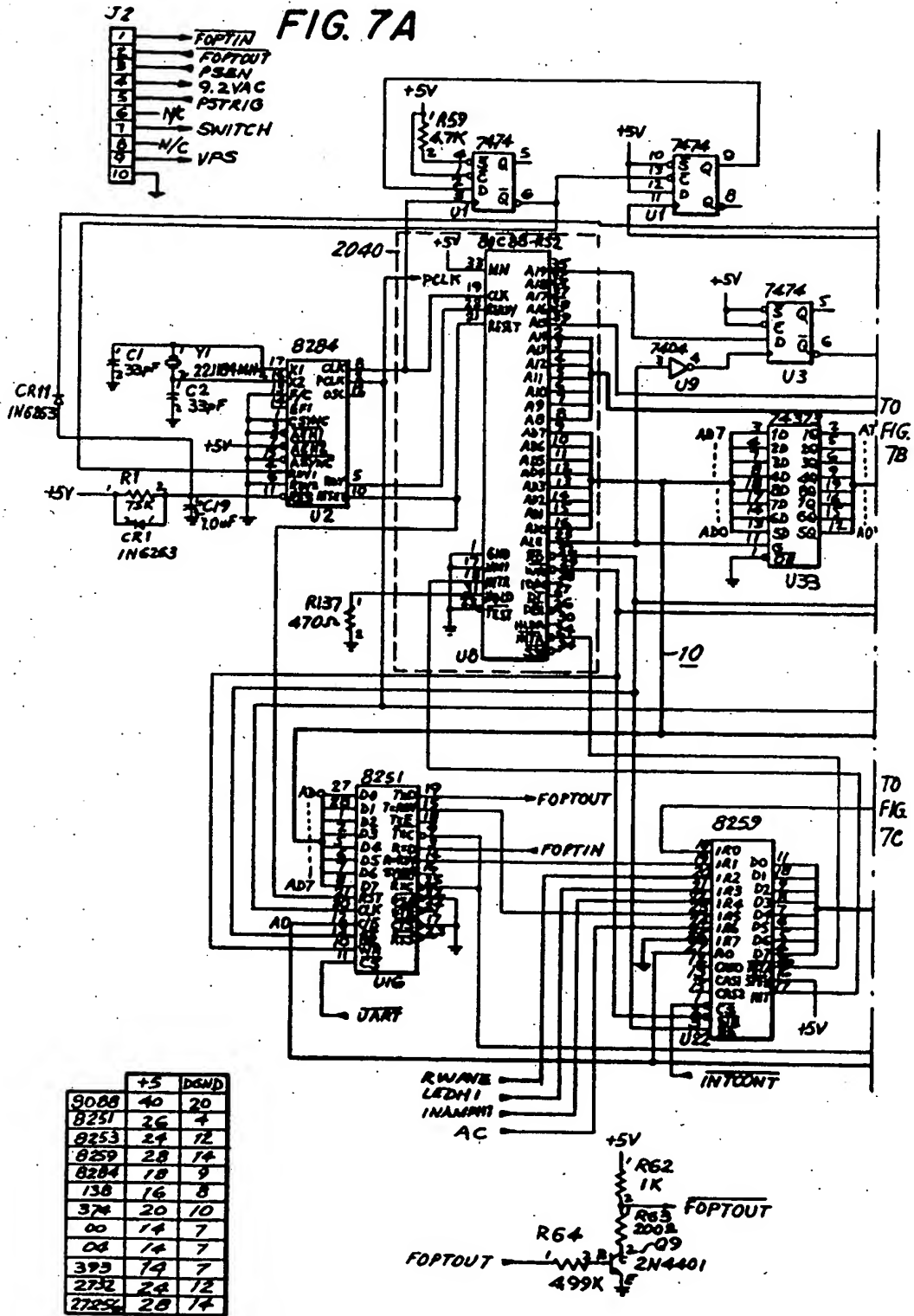
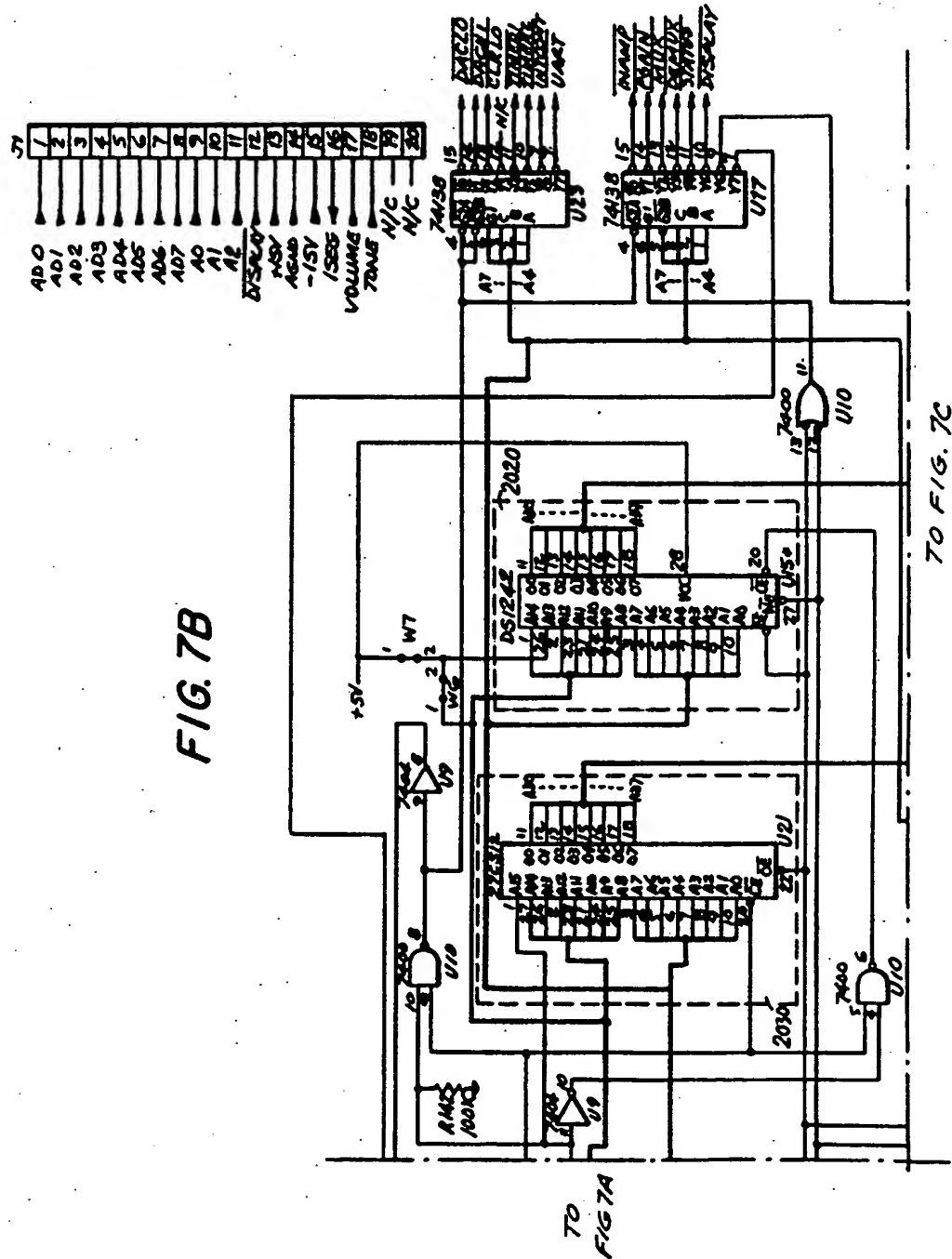
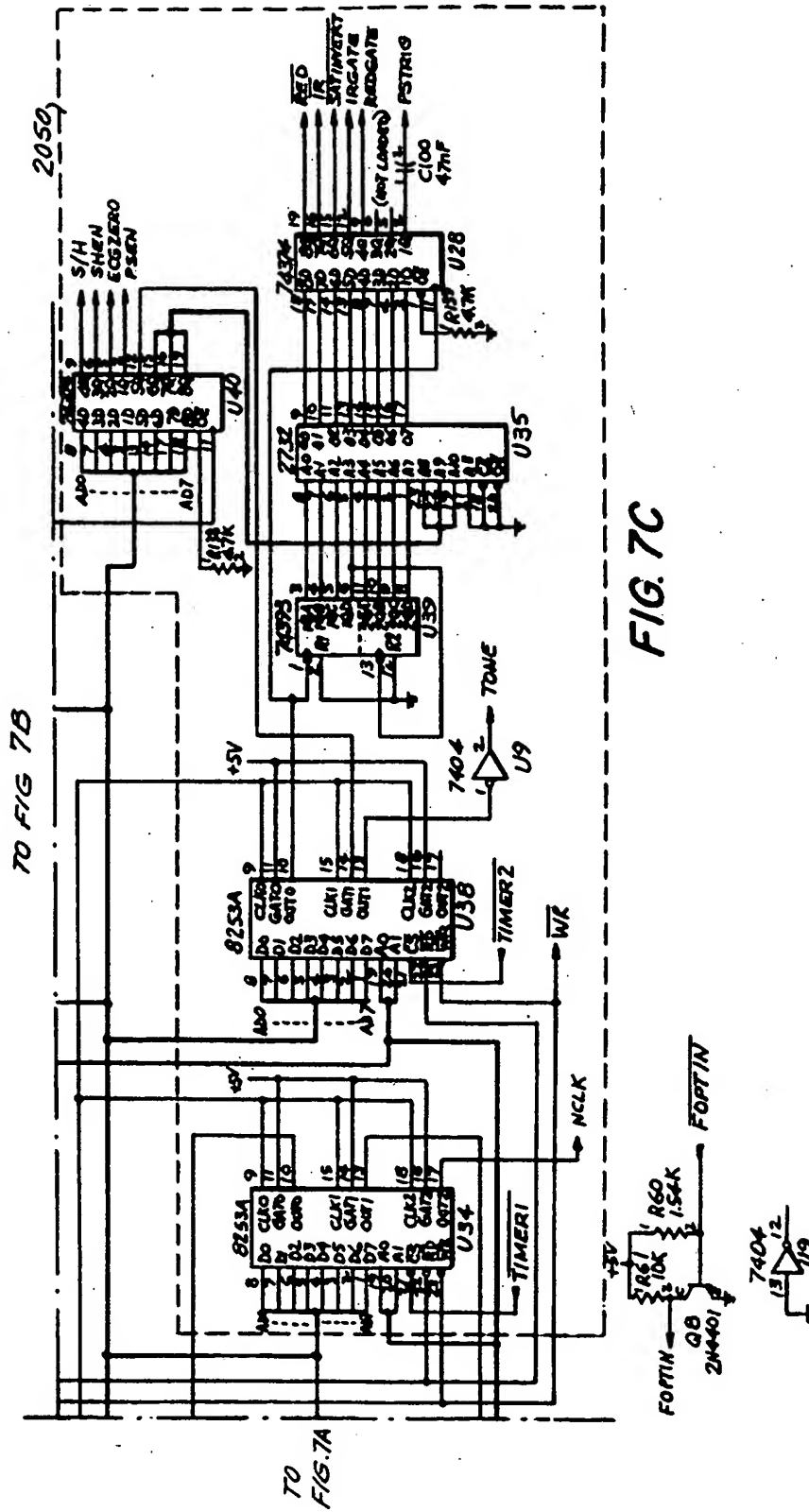


FIG. 6B

FIG. 7A







FOURIER OXYMETER FLOWCHART **FIG. 9**